UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to_____

Commission File Number: 001-35703

PUMA BIOTECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0683487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

10880 Wilshire Boulevard, Suite 2150, Los Angeles, CA 90024
(Address of principal executive offices) (Zip code)

(424) 248-6500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	PBYI	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date. 40,361,916 shares of Common Stock, par value $0.0001 per share, were outstanding as of April 30, 2021.

PUMA BIOTECHNOLOGY, INC.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Any statements about our expectations, beliefs, plans, objectives, assumptions, future events or performance are not historical facts and may be forward looking. These forward-looking statements include, but are not limited to, statements about:

- the commercialization of NERLYNX® (neratinib);
- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the impact of the global COVID-19 pandemic, and measures to control the spread of COVID-19, on business, financial condition, results of operations and ongoing trials;
- the anticipated timing of regulatory filings;
- the regulatory approval of our drug candidates;
- our use of clinical research organizations and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- efforts of our sub-licensees to obtain regulatory approval and commercialize NERLYNX in areas outside the United States;
- our ability to market any of our products;
- our expectations regarding our costs and expenses;
- our anticipated capital requirements and estimates regarding our needs for additional financing;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our intention and ability to vigorously defend against any litigation to which we are or may become party;
- our estimates for damages that we may be required to pay in connection with the class action lawsuit to which we are a party;
- our ability to attract and retain key personnel; and
- our ability to obtain adequate financing.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe,” “intend” and similar words or phrases. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Discussions containing these forward-looking statements may be found throughout this Quarterly Report, including, in Part I, the section entitled “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These forward-looking statements involve risks and uncertainties, including the risks discussed in Part I, Item 1A. “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2020 that could cause our actual results to differ materially from those in the forward-looking statements. Such risks should be considered in evaluating our prospects and future financial performance. We undertake no obligation to update the forward-looking statements or to reflect events or circumstances after the date of this document.

Item 1. Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,653	$ 85,293
Marketable securities	13,397	8,096
Accounts receivable, net of allowance for credit loss of $1,000 and $1,000	26,158	25,543
Inventory, net	7,745	3,454
Prepaid expenses, current	11,589	11,262
Restricted cash, current	8,850	8,850
Other current assets	373	3,641
Total current assets	163,765	146,139
Lease right-of-use assets, net	15,834	16,404
Property and equipment, net	2,283	2,481
Intangible assets, net	72,136	74,140
Restricted cash, long-term	3,311	3,311
Prepaid expenses and other, long-term	1,330	1,745
Total assets	$ 258,659	$ 244,220
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 10,654	$ 12,076
Accrued expenses, current	79,284	61,325
Accrued in-licensed rights, current	21,301	20,993
Post-marketing commitment liability, current	3,092	2,481
Lease liabilities, current	3,220	3,094
Current portion of long-term debt	22,857	14,286
Total current liabilities	140,408	114,255
Accrued expenses, long-term	1,140	25,963
Lease liabilities, long-term	18,710	19,549
Post-marketing commitment liability, long-term	5,618	6,379
Long-term debt	76,346	84,025
Total liabilities	242,222	250,171
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Common stock - $.0001 par value per share; 100,000,000 shares authorized; 40,324,263 shares issued and outstanding at March 31, 2021 and 40,086,387 issued and outstanding at December 31, 2020	4	4
Additional paid-in capital	1,337,536	1,331,676
Accumulated deficit	(1,321,103)	(1,337,631)
Total stockholders' equity (deficit)	16,437	(5,951)
Total liabilities and stockholders' equity (deficit)	$ 258,659	$ 244,220

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	For the Three Months Ended March 31,	
	2021	**2020**
Revenue:		
Product revenue, net	$ 45,816	$ 48,609
License revenue	50,000	2,000
Royalty revenue	2,353	608
Total revenue	98,169	51,217
Operating costs and expenses:		
Cost of sales	29,557	9,076
Selling, general and administrative	28,238	30,937
Research and development	20,228	25,455
Total operating costs and expenses	78,023	65,468
Income (loss) from operations	20,146	(14,251)
Other income (expenses):		
Interest income	13	386
Interest expense	(3,450)	(3,068)
Legal verdict expense	(185)	(93)
Other income	42	93
Total other expenses	(3,580)	(2,682)
Net income (loss) before income taxes	$ 16,566	$ (16,933)
Income tax expense	(38)	—
Net income (loss)	$ 16,528	$ (16,933)
Net income (loss) per share of common stock—basic	$ 0.41	$ (0.43)
Net income (loss) per share of common stock—diluted	$ 0.40	$ (0.43)
Weighted-average shares of common stock outstanding—basic	40,260,864	39,291,162
Weighted-average shares of common stock outstanding—diluted	40,894,868	39,291,162

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2021	2020
Net income (loss)	$ 16,528	$ (16,933)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities, net of tax of $0 and $0	—	(63)
Reclassifications of gain on available-for-sale securities, included in "Other income (expenses)", net of tax of $0 and $0	—	3
Comprehensive income (loss)	$ 16,528	$ (16,993)

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

For the Three Months Ended March 31, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2020	40,086,387	$ 4	$ 1,331,676	$ —	$ (1,337,631)	$ (5,951)
Stock-based compensation	—	—	5,860	—	—	5,860
Shares issued or restricted stock units vested under employee stock plans	237,876	—	—	—	—	—
Net income	—	—	—	—	16,528	16,528
Balance at March 31, 2021	40,324,263	$ 4	$ 1,337,536	$ —	$ (1,321,103)	$ 16,437

For the Three Months Ended March 31, 2020

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	39,203,304	$ 4	$ 1,295,033	$ 62	$ (1,277,636)	$ 17,463
Stock-based compensation	—	—	8,907	—	—	8,907
Shares issued or restricted stock units vested under employee stock plans	113,917	—	—	—	—	—
Reclassification of gain on available-for-sale securities	—	—	—	3	—	3
Unrealized loss on available-for-sale securities	—	—	—	(63)	—	(63)
Net loss	—	—	—	—	(16,933)	(16,933)
Balance at March 31, 2020	39,317,221	$ 4	$ 1,303,940	$ 2	$ (1,294,569)	$ 9,377

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

PUMA BIOTECHNOLOGY, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2021	**2020**
Operating activities:		
Net income (loss)	$ 16,528	$ (16,933)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,951	1,916
Stock-based compensation	5,860	8,907
Changes in operating assets and liabilities:		
Accounts receivable, net	(615)	(2,646)
Inventory, net	(4,291)	(127)
Prepaid expenses and other	88	(1,140)
Other current assets	3,268	18
Accounts payable	(1,422)	(1,928)
Accrued expenses and other	(6,556)	434
Deferred rent	—	(41)
Post-marketing commitment liability	(150)	—
Net cash provided by (used in) operating activities	15,661	(11,540)
Investing activities:		
Purchase of available-for-sale securities	(10,696)	—
Maturity of available-for-sale securities	5,395	34,377
Net cash (used in) provided by investing activities	(5,301)	34,377
Net increase in cash, cash equivalents and restricted cash	10,360	22,837
Cash, cash equivalents and restricted cash, beginning of period	97,454	73,210
Cash, cash equivalents and restricted cash, end of period	$ 107,814	$ 96,047
Supplemental disclosures of non-cash investing and financing activities:		
Intangibles in accrued expenses	$ 20,000	$ —
Property and equipment purchases in accounts payable	$ —	$ 13
Supplemental disclosure of cash flow information:		
Interest paid	$ 2,250	$ 2,275
Income taxes paid	$ 12	$ —

See Accompanying Notes to the Unaudited Condensed Consolidated Financial Statements

Note 1—Business and Basis of Presentation:

Business:

Puma Biotechnology, Inc., or the Company, is a biopharmaceutical company based in Los Angeles, California with a focus on the development and commercialization of innovative products to enhance cancer care. The Company in-licenses from Pfizer, Inc., or Pfizer, the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357, as well as certain related compounds. Neratinib is a potent irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors HER1, HER2 and HER4. Currently, the Company is primarily focused on the development and commercialization of the oral version of neratinib, and its most advanced drug candidates are directed at the treatment of HER2-positive breast cancer and HER2 mutated cancers. The Company believes that neratinib has clinical application in the treatment of several other cancers as well, including other tumor types that over-express or have a mutation in HER2 or EGFR, such as breast cancer, cervical cancer, lung cancer or other solid tumors.

The Company has two subsidiaries, Puma Biotechnology Ltd., a United Kingdom company, and Puma Biotechnology, B.V., a Netherlands company. These subsidiaries were established for the purpose of legal representation in the United Kingdom and the European Union.

Basis of Presentation:

The Company has incurred significant operating losses since its inception. The Company believes that it will continue to incur net losses and may incur negative net cash flows from operating activities through the drug development process and global commercialization. In 2017, the Company received U.S. Food and Drug Administration, or FDA, approval for its first product, NERLYNX® (neratinib), formerly known as PB272 (neratinib, oral), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. Following FDA approval in July 2017, NERLYNX became available by prescription in the United States, and the Company commenced commercialization.

In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.

In 2018, the European Commission, or EC, granted marketing authorization for NERLYNX in the European Union for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy.

The Company is required to make substantial payments to Pfizer upon the achievement of certain milestones and has contractual obligations for clinical trial contracts.

The Company has entered into other exclusive sub-license agreements with various parties to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved, in many regions outside the United States, including Europe (excluding Russia and Ukraine), Australia, Canada, China, Southeast Asia, Israel, Mexico, South Korea, and various countries and territories in Central and South America. The Company plans to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved.

The Company has reported net income of approximately $16.5 million and cash flows from operations of approximately $15.7 million for the three months ended March 31, 2021. The Company's commercialization, research and development or marketing efforts may require funding in addition to the cash and cash equivalents totaling approximately $95.7 million and marketable securities totaling approximately $13.4 million available at March 31, 2021. The Company believes that its existing cash and cash equivalents and marketable securities as of March 31, 2021 and proceeds that will become available to the Company through product sales and sub-license payments are sufficient to satisfy its operating cash and needs for at least one year after the filing of the Quarterly Report on Form 10-Q in which these financial statements are included. The Company continues to remain dependent on its ability to obtain sufficient funding to sustain operations and continue to successfully commercialize neratinib in the United States. While the Company has been successful in raising capital in the past, there can be no assurance that it will be able to do so in the future. The Company's ability to obtain funding may be adversely impacted by uncertain market conditions, including the COVID-19 pandemic, the Company's success in commercializing neratinib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time. Additionally, the terms of the Company's loan and security agreement place restrictions on the Company's ability to operate the business and on the Company's financial flexibility, and the Company may be unable to achieve the revenue necessary to satisfy the minimum revenue covenants as specified in the agreement.

Since its inception through March 31, 2021, the Company's financing has primarily been proceeds from product and license revenue, public offerings of its common stock, private equity placements, and borrowings under its loan and security agreement.

Note 2—Significant Accounting Policies:

The significant accounting policies followed in the preparation of these unaudited consolidated financial statements are as follows:

Principles of Consolidation:

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Segment Reporting:

Management has determined that the Company operates in one business segment, which is the development and commercialization of innovative products to enhance cancer care.

Use of Estimates:

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the balance sheet, and reported amounts of revenues and expenses for the period presented. Accordingly, actual results could differ from those estimates.

Significant estimates include estimates for variable consideration for which reserves were established. These estimates are included in the calculation of net revenues and include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products.

Net Income (Loss) per Share of Common Stock:

Basic net income (loss) per share of common stock is computed by dividing net income (loss) available to common stockholders by the weighted-average number of shares of common stock outstanding during the periods presented, as required by Accounting Standards Codification, or ASC, 260, *Earnings per Share*. For purposes of calculating diluted net income (loss) per share of common stock, the denominator includes both the weighted-average number of shares of common stock outstanding and the number of dilutive common stock equivalents, such as stock options, restricted stock units, or RSUs, and warrants. A common stock equivalent is not included in the denominator when calculating diluted earnings per common share if the effect of such common stock equivalent would be anti-dilutive and a net loss is reported. For the three months ended March 31, 2021, potentially dilutive securities excluded from the calculations were 4,960,445 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 1,741,770 shares underlying RSUs that were subject to vesting and were antidilutive. For the three months ended March 31, 2020, potentially dilutive securities excluded from the calculations were 4,330,242 shares issuable upon exercise of options, 2,116,250 shares issuable upon exercise of a warrant, and 2,274,100 shares underlying RSUs that were subject to vesting and were antidilutive. The 2,116,250 shares underlying the warrant will not have an impact on our diluted net income (loss) per share until the average market price of our common stock exceeds the exercise price of $16 per share. Refer to Note 11 for further details about the warrant.

A reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share of common stock computations is as follows (in thousands, except per share amounts):

	For the Three Months Ended March 31,	
	2021	2020
Numerator:		
Net income (loss)	$ 16,528	$ (16,933)
Denominator:		
Weighted average common stock outstanding for basic net income (loss) per share	40,261	39,291
Net effect of dilutive common stock equivalents	634	—
Weighted average common stock outstanding for diluted net income (loss) per share	40,895	39,291
Net income (loss) per share of common stock		
Basic	$ 0.41	$ (0.43)
Diluted	$ 0.40	$ (0.43)

Revenue Recognition:

Under ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, the Company recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services. The Company had no contracts with customers until the FDA approved NERLYNX on July 17, 2017. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with specialty pharmacies and specialty distributors in the United States to distribute NERLYNX. These arrangements are the Company's initial contracts with customers. The Company has determined that these sales channels with customers are similar.

Product Revenue, Net:

The Company sells NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. These customers subsequently resell the Company's products to patients and certain medical centers or hospitals. In addition to distribution agreements with these customers, the Company enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the specialty pharmacy or specialty distributor, as applicable, obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenue is recorded net of applicable reserves for variable consideration, including discounts and allowances. The Company's payment terms range between 10 and 68 days.

Shipping and handling costs for product shipments occur prior to the customer obtaining control of the goods and are recorded in cost of sales.

If taxes should be collected from customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three months ended March 31, 2021 and 2020.

Reserves for Variable Consideration:

Revenue from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the related sales, and are classified as reductions of accounts receivable, net when the right of offset exists in accordance with ASU 2013-1, *Balance Sheet (Topic 210): Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities,* or as a current liability. These estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a significant reversal of revenue would not be probable to occur in a future period for the estimates detailed below as of March 31, 2021 and, therefore, the transaction price was not reduced further during the quarter ended March 31, 2021. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances:

The Company generally provides customers with discounts, which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. The reserve for discounts is established in the same period that the related revenue is recognized, together with reductions to accounts receivable, net on the consolidated balance sheets. In addition, the Company compensates its customers for sales order management, data, and distribution services. The Company has determined such services received to date are not distinct from the Company's sale of products to its customers and, therefore, these payments have been recorded as a reduction of revenue within the statements of operations.

Product Returns:

Consistent with industry practice, the Company offers the specialty pharmacies and specialty distributors that are its customers limited product return rights for damaged and expiring product, provided it is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of product revenue, net in the period the related product revenue is recognized, as well as a reduction to accounts receivable, net on the consolidated balance sheets. The Company currently estimates product returns using its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has an insignificant amount of returns to date and believes that returns of its products will continue to be minimal.

Provider Chargebacks and Discounts:

Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to its customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. The reserve for chargebacks is established in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and a reduction to accounts receivable, net on the consolidated balance sheets. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's notification to the Company of the resale. Chargebacks consist of credits the Company expects to issue for units that remain in the distribution channel at each reporting period-end that the Company expects will be sold to qualified healthcare providers and chargebacks that customers have claimed, but for which the Company has not yet issued a payment.

Government Rebates:

The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses on the consolidated balance sheets. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimates of future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Payor Rebates:

The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue, net and the establishment of a current liability, which is included in accrued expenses on the consolidated balance sheets.

Other Incentives:

Other incentives the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included as a component of accrued expenses on the consolidated balance sheets.

License Revenue:

The Company also recognizes license revenue under certain of the Company's sub-license agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. The Company evaluates these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, upfront fees that are not contingent on any future performance and require no consequential continuing involvement by the Company, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. The Company defers recognition of non-refundable upfront license fees if the performance obligations are not satisfied.

Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved.

If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost-plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure.

Since 2018, the Company has entered into sub-license agreements with certain sub-licensees in territories outside of the United States. These sub-licensing agreements grant certain intellectual property rights and set forth various respective obligations with respect to actions such as development, pursuit and maintenance of regulatory approvals, commercialization and supply of NERLYNX in the sub-licensees' respective territories.

License fees under the sub-license agreements include one-time upfront payments when each sub-license agreement was executed and potential additional one-time milestone payments due to the Company upon successful completion of certain performance obligations, such as achieving regulatory approvals or sales target thresholds, and potential double-digit royalties on sales of the licensed product, calculated as a percentage of net sales of the licensed product throughout each sub-licensee's respective territory.

During the first quarter of 2021, the Company entered into an amendment to an existing sub-license agreement granting the sub-licensee development, manufacturing and commercial rights to NERLYNX in greater China. Pursuant to the amendment, the Company received and recognized as license revenue an upfront payment of $50.0 million during the first quarter of 2021.

The beginning balance of accounts receivable, net on the Company's consolidated balance sheet for license revenue from the sub-license agreements for the three months ended March 31, 2021 was $2.5 million. As of March 31, 2021, $2.0 million in license revenue from the sub-license agreements is included in accounts receivable, net and $1.0 million in the allowance for credit loss on the consolidated balance sheet. As of March 31, 2021, the total potential milestone payments that would be due to the Company upon achievement of all respective performance obligations under the sub-license agreements is approximately $581.6 million. At this time, the Company cannot estimate if or when these milestone-related performance obligations might be achieved.

Royalty Revenue:

For sub-license agreements that are within the scope of ASC 606, the Company recognizes revenue when the related sales occur in accordance with the sales-based royalty exception under ASC 606-10-55-65. Royalty revenue consists of consideration earned related to international sales of NERLYNX made by the Company's sub-licensees in their respective territories. The Company recognizes royalty revenue when the performance obligations have been satisfied. Royalty revenue was $2.4 million for the three months ended March 31, 2021.

Legal Contingencies and Expense:

For legal contingencies, the Company accrues a liability for an estimated loss if the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated. Legal fees and expenses are expensed as incurred based on invoices or estimates provided by legal counsel. The Company periodically evaluates available information, both internal and external, relative to such contingencies and adjusts the accrual as necessary. The Company determines whether a contingency should be disclosed by assessing whether a material loss is deemed reasonably possible. In determining whether a loss should be accrued, the Company evaluates, among other factors, the degree of probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of the loss (see Note 13-Commitments and Contingencies).

Royalty Expenses:

Royalties incurred in connection with the Company's license agreement with Pfizer, as disclosed in Note 13—Commitments and Contingencies, are expensed to cost of sales as revenue from product sales is recognized.

Research and Development Expenses:

Research and development expenses, or R&D Expenses, are charged to operations as incurred. The major components of R&D Expenses include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials, and allocations of various overhead costs. Clinical trial expenses include, but are not limited to, investigator fees, site costs, comparator drug costs, and clinical research organization, or CRO, costs. In the normal course of business, the Company contracts with third parties to perform various clinical trial activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variations from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients and the completion of portions of the clinical trial or similar conditions. The Company's accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites, cooperative groups and CROs. As actual costs become known, the Company adjusts its accruals in that period.

In instances where the Company enters into agreements with third parties for clinical trials and other consulting activities, upfront amounts are recorded to prepaid expenses and other in the accompanying consolidated balance sheets and expensed as services are performed or as the underlying goods are delivered. If the Company does not expect the services to be rendered or goods to be delivered, any remaining capitalized amounts for non-refundable upfront payments are charged to expense immediately. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables.

Costs related to the acquisition of technology rights and patents for which development work is still in process are charged to operations as incurred and considered a component of R&D Expenses.

Stock-Based Compensation:

Stock Option Awards:

ASC Topic 718, *Compensation-Stock Compensation*, or ASC 718, requires the fair value of all share-based payments to employees and nonemployees, including grants of stock options, to be recognized in the statement of operations over the requisite service period. Under ASC 718, employee and nonemployee option grants are generally valued at the grant date and those valuations do not change once they have been established. The fair value of each option award is estimated on the grant date using the Black-Scholes Option Pricing Method. As allowed by ASC 718, the Company's estimate of expected volatility is based on its average volatilities using its past eight years of publicly traded history. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant valuation. Option forfeitures are estimated when the option is granted to reduce the option expense to be recognized over the life of the award. The estimated forfeiture rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The option expense is adjusted upon the actual forfeiture of a stock option grant and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Due to its limited history of stock option exercises, the Company uses the simplified method to determine the expected life of the option grants. Compensation expense related to modified stock options is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Restricted Stock Units:

RSUs are valued on the grant date and the fair value of the RSUs is equal to the market price of the Company's common stock on the grant date. The RSU expense is recognized over the requisite service period. When the requisite service period begins prior to the grant date (because the service inception date occurs prior to the grant date), the Company is required to begin recognizing compensation cost before there is a measurement date (i.e., the grant date). The service inception date is the beginning of the requisite service period. If the service inception date precedes the grant date, accrual of compensation cost for periods before the grant date shall be based on the fair value of the award at the reporting date. In the period in which the grant date occurs, cumulative compensation cost shall be adjusted to reflect the cumulative effect of measuring compensation cost based on fair value at the grant date rather than the fair value previously used at the service inception date (or any subsequent reporting date). RSU forfeitures are estimated when the RSU is granted to reduce the RSU expense to be recognized over the life of the award. The estimated forfeiture rate considers historical employee turnover rates stratified into employee pools, actual forfeiture experience and other factors. The RSU expense is adjusted upon the actual forfeiture of an RSU grant and the Company periodically revises the estimated forfeiture rate in subsequent periods if actual forfeitures differ from those estimates. Compensation expense related to modified restricted stock units is measured based on the fair value for the awards as of the modification date. Any incremental compensation expense arising from the excess of the fair value of the awards on the modification date compared to the fair value of the awards immediately before the modification date is recognized at the modification date or ratably over the requisite service period, as appropriate.

Warrants:

Warrants (refer to Note 11 for further details) granted to employees and nonemployees are normally valued at the fair value of the instrument on the grant date and are recognized in the statement of operations over the requisite service period. When the requisite service period precedes the grant date and a market condition exists in the warrant, the Company values the warrant using the Monte Carlo Simulation Method. When the terms of the warrant become fixed, the Company values the warrant using the Black-Scholes Option Pricing Method. As allowed by ASC 718, the Company's estimate of expected volatility is based on its average volatilities using its publicly traded history. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the time of grant valuation. In determining the value of the warrant until the terms are fixed, the Company factors in the probability of the market condition occurring and several possible scenarios. When the requisite service period precedes the grant date and is deemed to be complete, the Company records the fair value of the warrant at the time of issuance as an equity stock-based compensation transaction. The grant date is determined when all pertinent information, such as exercise price and quantity are known.

Income Taxes:

The Company follows ASC Topic 740, *Income Taxes*, or ASC 740, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are based on the differences between the consolidated financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The standard addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such a position should be measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. ASC 740 also provides guidance on de-recognition, classification, interest and penalties on income taxes, accounting in interim periods and requires increased disclosures. As of March 31, 2021, the Company's uncertain tax position reserves include a reserve for its R&D credits.

Financial Instruments:

The carrying value of financial instruments, such as cash equivalents, accounts receivable and accounts payable, approximate their fair value because of their short-term nature. The carrying value of long-term debt approximates its fair value as the principal amounts outstanding are subject to variable interest rates that are based on market rates, which are regularly reset.

Cash and Cash Equivalents:

The Company classifies all highly liquid instruments with an original maturity of three months or less as cash equivalents.

Restricted Cash:

Restricted cash represents cash held at financial institutions that is pledged as collateral for stand-by letters of credit for lease and legal verdict commitments. The lease-related letters of credit will lapse at the end of the respective lease terms through 2026. At March 31, 2021 and December 31, 2020, the Company had restricted cash in the amount of $12.2 million.

Investment Securities:

The Company classifies all investment securities (short-term and long-term) as available-for-sale, as the sale of such securities may be required prior to maturity to implement management's strategies. These securities are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis. In accordance with ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, credit losses on available-for-sale securities are reported using an expected loss model and recorded to an allowance. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method. Interest income is recognized when earned.

Assets Measured at Fair Value on a Recurring Basis:

ASC Topic 820, *Fair Value Measurement*, or ASC 820, provides a single definition of fair value and a common framework for measuring fair value as well as disclosure requirements for fair value measurements used in financial statements. Under ASC 820, fair value is determined based upon the exit price that would be received by a company to sell an asset or paid by a company to transfer a liability in an orderly transaction between market participants, exclusive of any transaction costs. Fair value measurements are determined by either the principal market or the most advantageous market. The principal market is the market with the greatest level of activity and volume for the asset or liability. Absent a principal market to measure fair value, the Company uses the most advantageous market, which is the market from which the Company would receive the highest selling price for the asset or pay the lowest price to settle the liability, after considering transaction costs. However, when using the most advantageous market, transaction costs are only considered to determine which market is the most advantageous and these costs are then excluded when applying a fair value measurement. ASC 820 creates a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below, with Level 1 having the highest priority and Level 3 having the lowest.

Level 1:Quoted prices in active markets for identical assets or liabilities.

Level 2:Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.

Level 3:Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

Following are the major categories of assets measured at fair value on a recurring basis as of March 31, 2021 and December 31, 2020, using quoted prices in active markets for identical assets (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3) (in thousands):

March 31, 2021	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 66,424	$ —	$ —	$ 66,424
Commercial paper	—	11,093	—	11,093
Corporate bonds	—	2,304	—	2,304
Totals	$ 66,424	$ 13,397	$ —	$ 79,821

December 31, 2020	Level 1	Level 2	Level 3	Total
Cash equivalents	$ 59,919	$ 11,798	$ —	$ 71,717
Commercial paper	—	8,096	—	8,096
Totals	$ 59,919	$ 19,894	$ —	$ 79,813

The Company's investments in commercial paper, corporate bonds and U.S. government securities are exposed to price fluctuations. The fair value measurements for commercial paper, corporate bonds and U.S. government securities are based upon the quoted prices of similar items in active markets multiplied by the number of securities owned.

The following tables summarize the Company's short-term investments (in thousands):

March 31, 2021	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 66,424	$ —	$ —	$ 66,424
Commercial paper	Less than 1	11,093	—	—	11,093
Corporate bonds	Less than 1	2,304	—	—	2,304
Totals		$ 79,821	$ —	$ —	$ 79,821

December 31, 2020	Maturity (in years)	Amortized cost	Unrealized Gains	Unrealized Losses	Estimated fair value
Cash equivalents		$ 71,717	$ —	$ —	$ 71,717
Commercial paper	Less than 1	8,096	—	—	8,096
Totals	Less than 1	$ 79,813	$ —	$ —	$ 79,813

Concentration of Risk:

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash and cash equivalents, marketable securities, and accounts receivable, net. The Company's cash and cash equivalents and restricted cash in excess of the Federal Deposit Insurance Corporation and the Securities Investor Protection Corporation insured limits at March 31, 2021, were approximately $107.6 million. The Company does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held. Pursuant to the Company's internal investment policy, investments must be rated A-1/P-1 or better by Standard and Poor's Rating Service and Moody's Investors Service at the time of purchase.

The Company sells its products in the United States primarily through specialty pharmacies and specialty distributors. Therefore, wholesale distributors and large pharmacy chains account for a large portion of its accounts receivables, net and product revenues, net. The creditworthiness of its customers is continuously monitored, and the Company has internal policies regarding customer credit limits. The Company estimates an allowance for doubtful accounts primarily based on the credit worthiness of its customers, historical payment patterns, aging of receivable balances and general economic conditions. The Company recorded $0 and $1.0 million as an allowance for credit loss for the periods ended March 31, 2021 and December 31, 2020, respectively.

The Company's success depends on its ability to successfully commercialize NERLYNX. The Company currently has a single product and limited commercial sales experience, which makes it difficult to evaluate its current business, predict its future prospects and forecast financial performance and growth. The Company has invested a significant portion of its efforts and financial resources in the development and commercialization of the lead product, NERLYNX, and expects NERLYNX to constitute the vast majority of product revenue for the foreseeable future.

The Company relies exclusively on third parties to formulate and manufacture NERLYNX and its drug candidates. The commercialization of NERLYNX and any other drug candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide sufficient quantities of product or fail to do so at acceptable quality levels or prices. The Company has no experience in drug formulation or manufacturing and does not intend to establish its own manufacturing facilities. The Company lacks the resources and expertise to formulate or manufacture NERLYNX and other drug candidates. While the drug candidates were being developed by Pfizer, both the drug substance and drug product were manufactured by third-party contractors. The Company is using the same third-party contractors to manufacture, supply, store and distribute drug supplies for clinical trials and the commercialization of NERLYNX. If the Company is unable to continue its relationships with one or more of these third-party contractors, it could experience delays in the development or commercialization efforts as it locates and qualifies new manufacturers. The Company intends to rely on one or more third-party contractors to manufacture the commercial supply of drugs.

Inventory:

The Company values its inventories at the lower of cost and estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within the cost of sales in the consolidated statements of operations. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of sales in the consolidated statements of operations.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if any, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory that can be used in either the production of clinical or commercial product is recorded as R&D Expenses when selected for use in a clinical trial. Starter kits, provided to patients prior to insurance approval, are expensed by the Company to selling, general and administrative expense as incurred.

As of March 31, 2021, the Company's inventory balance consisted primarily of raw materials purchased subsequent to FDA approval of NERLYNX.

Property and Equipment, Net:

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which is generally three years for computer hardware and software, three years for phone equipment, and seven years for furniture and fixtures. Leasehold improvements are amortized using the straight-line method over the lesser of the useful life or the lease term. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

The Company reviews its long-lived assets used in operations for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, as required by ASC Topic 360, *Property, Plant, and Equipment,* or ASC 360. The Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows over the life of the asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would then determine the fair value of the long-lived asset and recognize an impairment loss for the amount in excess of the carrying value.

Leases:

ASC Topic 842, *Leases*, as adopted in the first quarter of 2019, requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset, or ROU asset. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance, as required by ASC 360. A significant indication of impairment of an ROU asset would include a change in the extent or manner in which the asset is being used. The Company must make assumptions which underlie the most significant and subjective estimates in determining whether any impairment exists. Those estimates, and the underlying assumptions, include estimates of future cash flow utilizing market lease rates and determination of fair value. If an ROU asset related to an operating lease is impaired, the carrying value of the ROU asset post-

impairment should be amortized on a straight-line basis through the earlier of the end of the useful life of the ROU asset or the end of the lease term. Post impairment, a lessee must calculate the amortization of the ROU asset and interest expense on the lease liability separately, although the sum of the two continues to be presented as a single lease cost. If a lease is planned to be abandoned with no intention of subleasing, the ROU asset should be assessed for impairment.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them. For additional information, see Note 6—Leases.

The Company leases office space and copy machines, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to extend or terminate a lease are considered in the lease term to the extent that the option is reasonably certain of exercise. The leases do not include options to purchase the leased property. The depreciable life of assets and leasehold improvements is limited by the expected lease term. Covenants imposed by the leases include letters of credit required to be obtained by the lessee.

The incremental borrowing rate, or IBR, represents the rate of interest the Company would expect to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. When determinable, the Company uses the rate implicit in the lease to determine the present value of lease payments. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company's average IBR for existing leases as of March 31, 2021 is 10.9%.

License Fees and Intangible Assets:

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale. The Company capitalizes technology licenses upon reaching technological feasibility.

The Company maintains definite-lived intangible assets related to the license agreement with Pfizer. These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated. Amortization costs are recorded as part of cost of sales.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value. In connection with the FDA approval of NERLYNX in July 2017, the Company triggered a one-time milestone payment pursuant to its license agreement with Pfizer. In June 2020, the Company entered into a letter agreement with Pfizer relating to the method of payment associated with a milestone payment under the Company's license agreement with Pfizer (see Note 13-Commitments and Contingencies). The Company capitalized the milestones as intangible assets and is amortizing the assets to cost of sales on a straight-line basis over the estimated useful life of the licensed patent through 2030. The Company recorded amortization expense related to its intangible assets of $2.0 million for the three months ended March 31, 2021. As of March 31, 2021 estimated future amortization expense related to the Company's intangible assets was approximately $6.0 million for the remainder of 2021 and $8.0 million for each year starting 2022 through 2029, and $2.0 million for 2030.

During the three months ended March 31, 2021, the Company agreed to settle its ongoing arbitration proceeding with CANbridge BIOMED Limited, or CANbridge, relating to an agreement in which the Company granted CANbridge an exclusive sub-license to develop and commercialize NERLYNX throughout greater China. The Company and CANbridge agreed to drop their respective claims against one another. At the same time, the Company entered into a separate transaction in which it agreed to pay CANbridge a one-time termination fee of $20.0 million in exchange for it returning to the Company all rights to NERLYNX in greater China. The Company expensed the $20.0 million one-time termination fee to cost of sales in the three months ended March 31, 2021.

Recently Issued Accounting Standards:

In December 2019, the FASB issued ASU No 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its Simplification Initiative to reduce the cost and complexity in accounting for income taxes. The amendments in ASU 2019-12 remove certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also amends other aspects of the guidance to help simplify and promote consistent application of GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2020, with early adoption permitted. ASU 2019-12 did not have a material effect on the Company's current financial position, results of operations or financial statement disclosures.

In October 2020, the FASB issued *ASU 2020-10*, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with SEC regulations. The Company adopted *ASU 2020-10* as of the reporting period beginning January 1, 2021. ASU 2020-10 did not have a material effect on the Company's current financial position, results of operations or financial statement disclosures.

Note 3—Accounts Receivable, Net:

Accounts receivable, net consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Trade accounts receivable	$ 22,800	$ 21,515
License revenue receivable	2,000	2,500
Royalty revenue receivable	2,358	2,528
Total accounts receivable	$ 27,158	$ 26,543
Allowance for credit losses	(1,000)	(1,000)
Total accounts receivable, net	$ 26,158	$ 25,543

Trade accounts receivable consist entirely of amounts owed from the Company's customers related to product sales. License revenue receivable represents an amount owed from a sub-licensee under a sub-license agreement. Royalty revenue receivable represents amounts owed related to royalty revenue recognized based on the Company's sub-licensees' sales in their respective territories in the periods ended March 31, 2021 and December 31, 2020.

For all accounts receivable, the Company recognized credit losses based on lifetime expected losses to selling, general and administrative expense in the consolidated statements of operations. In determining estimated credit losses, the Company evaluated its historical loss rates, current economic conditions and reasonable and supportable forecasts of future economic conditions. The Company recorded $0 and $1.0 million as a credit loss expense for the periods ended March 31, 2021 and December 31, 2020, respectively. The rollforward of the allowance for credit losses is as follows:

Allowance for credit losses (in thousands):	
Beginning balance at January 1, 2021	$ (1,000)
Provision for credit loss expense	—
Accounts receivable written-off	—
Recoveries	—
Total ending allowance balance as March 31, 2021	$ (1,000)

Note 4—Prepaid Expenses and Other:

Prepaid expenses and other consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Current:		
CRO services	$ 1,308	$ 1,550
Other clinical development	3,322	2,718
Insurance	2,733	3,708
Professional fees	1,083	651
Other	3,143	2,635
	11,589	11,262
Long-term:		
CRO services	198	518
Other clinical development	475	437
Other	657	790
	1,330	1,745
Totals	$ 12,919	$ 13,007

Other current prepaid amounts consist primarily of deposits, signing bonuses, licenses, subscriptions and software. Other long-term prepaid amounts consist primarily of deposits, signing bonuses, licenses, subscriptions, software, a capitalized sublease commission and a sublease tenant improvement allowance, net of amortization.

Note 5—Other Current Assets:

Other current assets consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Deposit for manufacturing costs	$ —	$ 3,376
Deferred rent	198	198
Other	175	67
Totals	$ 373	$ 3,641

Other current asset amounts consist primarily of a deposit, capitalized sublease commission and a sublease tenant improvement allowance, net of amortization.

Note 6—Leases:

In December 2011, the Company entered into a non-cancelable operating lease for office space in Los Angeles, California, which was subsequently amended in November 2012, December 2013, March 2014, July 2015, and December 2017. The initial term of the lease was for seven years and commenced on December 10, 2011. As amended, the Company rents approximately 65,656 square feet. The term of the lease runs until March 2026, and rent amounts payable by the Company increase approximately 3% per year. Concurrent with the execution of the lease, the Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $2.0 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets.

In June 2012, the Company entered into a long-term lease agreement for office space in South San Francisco, California, which was subsequently amended in May 2014 and July 2015. As amended, the Company rents approximately 29,470 square feet. The term of this lease runs until March 2026, with the option to extend for an additional five-year term, and rents payable by the Company increase approximately 3% per year. The Company provided the landlord an automatically renewable stand-by letter of credit in the amount of $1.1 million. The stand-by letter of credit is collateralized by a high-yield savings account, which is classified as restricted cash, long-term on the accompanying consolidated balance sheets.

The Company also leases copier equipment for use in the office spaces. Components of lease expense include fixed lease expense and variable lease expense of approximately $1.2 million and $0.1 million, respectively, for each of the three months ended March 31, 2021 and March 31, 2020. For purposes of determining straight-line rent expense, the lease term is calculated from the date the Company first takes possession of the facility, including any periods of free rent and any renewal option periods that the Company is reasonably certain of exercising. The Company's office and equipment leases generally have contractually specified minimum rent and annual rent increases that are included in the measurement of the ROU asset and related lease liability. Additionally, under these lease arrangements, the Company may be required to pay directly, or reimburse the lessors, for real estate taxes, insurance, utilities, maintenance and other operating costs. Such amounts are generally variable and therefore not included in the measurement of the ROU asset and related lease liability but are instead recognized as variable lease expense in selling, general and administrative costs in the consolidated statements of operations when they are incurred.

Supplemental cash flow information related to leases for the three months ended March 31, 2021:

Operating cash flows used for operating leases (in thousands)	$	1,380
Right-of-use assets obtained in exchange for new operating lease liabilities		—
Weighted average remaining lease term (in years)		5.0
Weighted average discount rate		10.9%

The future minimum lease payments under ASC 842 as of March 31, 2021 were as follows (in thousands):

		Amount
2021 (remaining)		4,054
2022		5,483
2023		5,631
2024		5,805
2025		5,983
Thereafter		1,508
Total minimum lease payments	$	28,464
Less: imputed interest		(6,534)
Total lease liabilities	**$**	**21,930**

In February 2019, the Company entered into a long-term sublease agreement for 12,429 square feet of the office space in Los Angeles, California. The term of the lease runs until March 2026 and rent amounts payable to the Company increase approximately 3% per year. The Company recorded operating sublease income of $0.1 million for the three months ended March 31, 2021, respectively, in other income (expenses) in the consolidated statements of operations.

The future minimum lease payments to be received as of March 31, 2021 were as follows (in thousands):

		Amount
2021 (remaining)	$	351
2022		481
2023		495
2024		510
2025		525
Thereafter		134
Total	**$**	**2,496**

Note 7—Property and Equipment, Net:

Property and equipment, net consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Leasehold improvements	$ 3,779	$ 3,779
Computer equipment	2,192	2,192
Telephone equipment	302	302
Furniture and fixtures	2,359	2,359
	8,632	8,632
Less: accumulated depreciation	(6,349)	(6,151)
Totals	$ 2,283	$ 2,481

For the three months ended March 31, 2021, the Company incurred depreciation expense of $0.2 million.

Note 8—Intangible Assets, Net:

Intangible assets, net consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Acquired and in-licensed rights	$ 90,000	$ 90,000
Less: accumulated amortization	(17,864)	(15,860)
Total intangible asset, net	$ 72,136	$ 74,140

For the three months ended March 31, 2021, the Company incurred amortization expense of $2.0 million. In June 2020, the Company entered into a letter agreement with Pfizer relating to the method of payment associated with a one-time milestone payment under the Company's license agreement with Pfizer (see Note 13-Commitments and Contingencies). The estimated remaining useful life of the intangible assets as of March 31, 2021 is 9.0 years.

Note 9—Accrued Expenses:

Accrued expenses consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Current:		
Accrued legal verdict expense	$ 47,731	$ 22,724
Accrued royalties	7,934	8,604
Accrued CRO services	1,795	3,474
Accrued variable consideration	9,050	9,014
Accrued bonus	2,039	7,788
Accrued compensation	5,135	4,820
Accrued other clinical development	1,512	1,904
Accrued professional fees	1,424	1,420
Accrued legal fees	1,599	383
Accrued manufacturing costs	476	752
Other	589	442
	79,284	61,325
Long-term:		
Accrued legal verdict expense	—	24,822
Accrued CRO services	934	908
Accrued other	206	233
	1,140	25,963
Totals	$ 80,424	$ 87,288

Accrued CRO services, accrued other clinical development expenses, and accrued legal fees represent the Company's estimates of such costs and are recognized as incurred. Accrued royalties represent royalties incurred in connection with the Company's license agreement with Pfizer. Accrued compensation includes accrued commissions and accrued vacation, which is accrued at the rate the employee earns vacation and reduced as vacation is used by the employee. Accrued variable consideration represents estimates of adjustments to product revenue, net for which reserves are established.

Current accrued legal verdict expense includes an estimate of $22.9 million that may be owed to the plaintiff as a result of the jury verdict in *Eshelman v. Puma Biotechnology, Inc., et al.* The Company estimates the high end of potential damages in the matter could be approximately $27.9 million; however, the actual amount of damages payable by the Company is still uncertain and will be ascertained only after completion of the appeal and any subsequent proceeding, and such amount could be greater than the amount of expense already recognized or the high end of the estimate.

Additionally, current accrued legal verdict expense includes the Company's estimate of $24.9 million that may be owed to class action participants as a result of the jury verdict in *Hsu v. Puma Biotechnology, Inc., et al*. While the final claims report received in *Hsu* reflects a total of $50.5 million in claimed damages, the Company intends to challenge these claims and estimates that actual claims could be as low as $24.9 million. The actual amount and timing of payment of damages in *Hsu* is uncertain and will be ascertained only after an extensive claims challenge process, the completion of post-trial proceedings and the exhaustion of any appeals. The Company has estimated the legal verdict expense for *Hsu* to be $24.9 million and has classified the accrual as current due to the uncertainty of the timing of the payment. Actual damages in the *Hsu* matter may be higher than the Company's estimate. In addition, on September 9, 2019, the Court entered an order specifying the rate of prejudgment interest to be awarded on any valid claims at the 52-week Treasury Bill rate.

Other current accrued expenses consist primarily of business license fees, one half of the portion of employer Social Security payroll taxes deferred under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, and other taxes, insurance and marketing fees.

Other long-term accrued expenses consist primarily of one half of the portion of employer Social Security payroll taxes deferred under the CARES Act, accrued compensation and deposit from a sublessee.

All accrued expenses are adjusted in the period the actual costs become known.

Note 10—Debt:

Long term debt consisted of the following (in thousands):

Loan and Security Agreement:

	March 31, 2021	Maturity Date
Total debt	$ 100,000	June 1, 2024
Accretion of final interest payment	3,675	
Less: current portion of long-term debt	(22,857)	
Less: deferred financing costs	(4,472)	
Total long-term debt, net	$ 76,346	

On June 28, 2019, or the Effective Date, the Company entered into an amendment and restatement of its loan and security agreement, which provided for a new credit facility, or the New Credit Facility, with Oxford Finance, LLC, or Oxford, as collateral agent, and the lenders party thereto from time to time, including Oxford, pursuant to which the Company repaid its outstanding debt, as well as all applicable exit and prepayment fees, owed to the lenders under its prior credit facility, using cash on hand and $100.0 million in new borrowings from the New Credit Facility. Under the New Credit Facility, the Company issued to Oxford new and/or replacement secured promissory notes in an aggregate principal amount for all such promissory notes of $100.0 million evidencing the New Credit Facility. No additional money remains available to the Company under the New Credit Facility.

The New Credit Facility is secured by substantially all of the Company's personal property other than its intellectual property. The Company also pledged 65% of the issued and outstanding capital stock of its subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V. The New Credit Facility limits the Company's ability to grant any interest in its intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The term loans under the New Credit Facility bear interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. The Company is required to make monthly interest-only payments on each term loan under the New Credit Facility commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through August 1, 2021, or the Amortization Date. Commencing on the Amortization Date, and continuing on the first calendar day of each calendar month thereafter, the Company will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender under the New Credit Facility, calculated pursuant to the New Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan under the New Credit Facility is due and payable in full on June 1, 2024, or the Maturity Date. Upon repayment of such term loans, the Company is also required to make a final payment to the lenders equal to 7.5% of the aggregate principal amount of such term loans outstanding as of the Effective Date. The effective interest rate as of March 31, 2021 was 12.75%.

At the Company's option, the Company may prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment occurs through and including the first anniversary of the funding date of such term loan, 2.0% of the amount prepaid if the prepayment occurs after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment occurs after the second anniversary of the funding date of such term loan and prior to the Maturity Date.

The New Credit Facility includes affirmative and negative covenants applicable to the Company, its current subsidiaries and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The Company must also achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of the Company, Oxford, as collateral agent, and the lenders under the New Credit Facility. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The New Credit Facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the New Credit Facility, including foreclosure against the property securing the New Credit Facility, including the Company's cash. These events of default include, among other things, the Company's failure to pay principal or interest due under the New Credit Facility, a breach of certain covenants under the New Credit Facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against the Company in an amount greater than $500,000 individually or in the aggregate that remains unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

On February 27, 2020, the Company and Oxford amended the New Credit Facility to establish the Company's minimum revenue thresholds for the trailing year-to-date periods ending March 31, June 30, September 30 and December 31, 2020 and the fiscal year 2021. On August 5, 2020 the Company and Oxford amended the New Credit Facility to amend the minimum revenue thresholds for the trailing year-to-date periods ending September 30 and December 31, 2020. On February 3, 2021, the Company and Oxford amended the New Credit Facility to establish the Company's minimum revenue thresholds for the trailing year-to-date periods ending March 31, June 30, September 30 and December 31, 2021.

As of March 31, 2021, there were $100.0 million in term loans outstanding under the New Credit Facility, representing all of the Company's long-term debt outstanding as of that date, and the Company was in compliance with all applicable covenants under the New Credit Facility.

The future minimum principal payments under the New Credit Facility as of March 31, 2021 were as follows (in thousands):

	Amount
2021 (remaining)	$ 14,286
2022	34,286
2023	34,286
2024	17,142
Thereafter	—
Total	**$ 100,000**

Deferred Financing Costs

Deferred financing costs consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Deferred financing costs	$ 8,668	$ 8,668
Less: accumulated amortization	(4,196)	(3,666)
Included in long-term debt	$ 4,472	$ 5,002

Deferred financing costs are financing costs related to the Company's outstanding debt. Amortization of debt issuance costs is expensed using the effective interest method and is included in interest expense in the consolidated statement of operations. For each of the three months ended March 31, 2021 and 2020, the Company recorded approximately $0.5 million of interest expense related to the amortization of debt issuance costs in the consolidated statements of operations.

Note 11—Stockholders' Equity:

Common Stock:

The Company issued 0 and 500 shares of common stock upon exercise of stock options during the three months ended March 31, 2021 and 2020, respectively. The Company issued 237,876 and 113,417 shares of common stock upon vesting of RSUs during the three months ended March 31, 2021 and 2020, respectively.

Authorized Shares:

The Company has 100,000,000 shares of stock authorized for issuance, all of which are common stock, par value $0.0001 per share.

Warrants:

In October 2011, the Company issued an anti-dilutive warrant to Alan Auerbach, the Company's founder and Chief Executive Officer. The warrant was issued to provide Mr. Auerbach with the right to maintain ownership of at least 20% of the Company's common stock in the event that the Company raised capital through the sale of its securities in the future.

In connection with the closing of a public offering in October 2012, the exercise price and number of shares underlying the warrant issued to Mr. Auerbach were established and, accordingly, the final value of the warrant became fixed. Pursuant to the terms of the warrant, Mr. Auerbach may exercise the warrant to acquire 2,116,250 shares of the Company's common stock at $16 per share until October 4, 2021.

Stock Options and Restricted Stock Units:

The Company's 2011 Incentive Award Plan, as amended, or the 2011 Plan, was adopted by the Company's Board of Directors on September 15, 2011. Pursuant to the 2011 Plan, the Company may grant incentive stock options and nonqualified stock options, as well as other forms of equity-based compensation. Incentive stock options may be granted only to employees, while consultants, employees, officers and directors are eligible for the grant of nonqualified options under the 2011 Plan. The maximum term of stock options granted under the 2011 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of incentive stock options granted under the 2011 Plan must be at least equal to the fair value of such shares on the date of grant. As of March 31, 2021, a total of 12,529,412 shares of the Company's common stock have been reserved for issuance under the 2011 Plan.

All of the options awarded by the Company have been "plain vanilla options" as determined by the SEC Staff Accounting Bulletin 107 - *Share Based Payment.* As of March 31, 2021, 6,771,081 shares of the Company's common stock are issuable upon the exercise of outstanding stock options and vesting of RSUs granted under the 2011 Plan and 1,051,438 shares of the Company's common stock are available for future issuance under the 2011 Plan. The fair value of options granted to employees and nonemployees was estimated using the Black-Scholes Option Pricing Method (see Note 2) with the following weighted-average assumptions used during the three months ended March 31:

	2021	2020
Dividend yield	0.0%	0.0%
Expected volatility	86.9%	102.7%
Risk-free interest rate	0.7%	1.0%
Expected life in years	5.81	5.80

The Company's 2017 Employment Inducement Incentive Award Plan, as amended, or the 2017 Plan, was adopted by the Company's Board of Directors on April 27, 2017. Pursuant to the 2017 Plan, the Company may grant stock options and RSUs, as well as other forms of equity-based compensation to employees, as an inducement to join the Company. The maximum term of stock options granted under the 2017 Plan is 10 years and the awards generally vest over a three-year period. The exercise price of stock options granted under the 2017 Plan must be at least equal to the fair market value of such shares on the date of grant. As of March 31, 2021, a total of 2,000,000 shares of the Company's common stock have been reserved for issuance under the 2017 Plan. As of March 31, 2021, 1,173,262 shares of the Company's common stock are issuable upon the exercise of outstanding stock options and vesting of RSUs granted under the 2017 Plan and 452,353 shares of the Company's common stock are available for future issuance under the 2017 Plan.

Stock-based compensation expense was as follows (in thousands):

	For the Three Months Ended March 31,	
	2021	2020
Stock-based compensation:		
Options -		
Selling, general, and administrative	$ 1,007	$ 920
Research and development	228	841
Restricted stock units -		
Selling, general, and administrative	2,594	3,772
Research and development	2,031	3,374
Total stock-based compensation expense	$ 5,860	$ 8,907

Activity with respect to options granted under the 2011 Plan and 2017 Plan is summarized as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	5,009,342	$ 71.42	5.1	$ 3,458
Granted	442,027	$ 12.02	9.9	
Expired	(33,729)	$ 77.55		
Outstanding at March 31, 2021	5,417,640	$ 66.53	5.2	$ 2,993
Nonvested at March 31, 2021	1,085,182	$ 11.26	9.3	$ 626
Exercisable	4,332,458	$ 80.38	4.2	$ 2,367

At March 31, 2021, total estimated unrecognized employee compensation cost related to non-vested stock options granted prior to that date was approximately $8.4 million, which is expected to be recognized over a weighted-average period of 2.1 years. At March 31, 2021, the total estimated unrecognized employee compensation cost related to non-vested RSUs was approximately $22.3 million, which is expected to be recognized over a weighted-average period of 2.0 years. The weighted-average grant date fair value of options granted during the three months ended March 31, 2021 and 2020 was $8.54 and $7.86 per share, respectively. The weighted average grant date fair value of RSUs awarded during the three months ended March 31, 2021 and 2020 was $12.30 and $10.74 per share, respectively.

Stock Option Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2020	899,672	$ 8.71
Granted	442,027	8.54
Vested/Issued	(256,517)	9.66
Nonvested shares at March 31, 2021	1,085,182	$ 8.42

Restricted Stock Unit Rollforward

	Shares	Weighted Average Grant-Date Fair Value
Nonvested shares at December 31, 2020	1,854,205	$ 13.51
Granted	999,272	12.30
Vested/Issued	(237,876)	17.60
Forfeited	(88,898)	13.62
Nonvested shares at March 31, 2021	2,526,703	$ 12.65

Note 12—401(k) Savings Plan:

During 2012, the Company adopted a 401(k) savings plan for the benefit of its employees. The Company is required to make matching contributions to the 401(k) plan equal to 100% of the first 3% of wages deferred by each participating employee and 50% on the next 2% of wages deferred by each participating employee. The Company incurred expenses for employer matching contributions of approximately $0.6 million and $0.4 million for the three months ended March 31, 2021 and 2020, respectively.

Note 13—Commitments and Contingencies:

Contractual Obligations:

Contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which the Company cannot reasonably predict future payment. The Company's contractual obligations result primarily from obligations for various contract manufacturing organizations and clinical research organizations, which include potential payments we may be required to make under our agreements. The contracts also contain variable costs and milestones that are hard to predict as they are based on such things as patients enrolled and clinical trial sites. The timing of payments and actual amounts paid under contract manufacturing organization, or CMO, and CRO agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations. Also, those agreements are cancelable upon written notice by the Company and, therefore, not long-term liabilities.

License Agreement:

In August 2011, the Company entered into an agreement pursuant to which Pfizer agreed to grant it a worldwide license for the development, manufacture and commercialization of PB272 neratinib (oral), PB272 neratinib (intravenous) and PB357, and certain related compounds. The license is exclusive with respect to certain patent rights owned by or licensed to Pfizer. Under the agreement, the Company is obligated to commence a new clinical trial for a product containing one of these compounds within a specified period of time and to use commercially reasonable efforts to complete clinical trials and to achieve certain milestones as provided in a development plan. From the closing date of the agreement through December 31, 2011, Pfizer continued to conduct the existing clinical trials on behalf of the Company at Pfizer's sole expense. At the Company's request, Pfizer has agreed to continue to perform certain services in support of the existing clinical trials at the Company's expense. These services will continue through the completion of the transitioned clinical trials. The license agreement "capped" the out of pocket expense the Company would incur to complete the then existing clinical trials. All agreed upon costs incurred by the Company above the "cost cap" would be reimbursed by Pfizer. The Company exceeded the "cost cap" during the fourth quarter of 2012. In accordance with the license agreement, the Company billed Pfizer for agreed upon costs above the "cost cap" until December 31, 2013.

On July 18, 2014, the Company entered into an amendment to the license agreement with Pfizer. The amendment amends the agreement to (1) reduce the royalty rate payable by the Company to Pfizer on sales of licensed products; (2) release Pfizer from its obligation to pay for certain out-of-pocket costs incurred or accrued on or after January 1, 2014 to complete certain ongoing clinical studies; and (3) provide that Pfizer and the Company will continue to cooperate to effect the transfer to the Company of certain records, regulatory filings, materials and inventory controlled by Pfizer as promptly as reasonably practicable.

As consideration for the license, the Company is required to make substantial payments upon the achievement of certain milestones totaling approximately $187.5 million if all such milestones are achieved. In connection with the FDA approval of NERLYNX in July of 2017, the Company triggered a one-time milestone payment pursuant to the agreement. In June 2020, the Company entered into a letter agreement, or the Letter Agreement, with Pfizer relating to the method of payment associated with a one-time milestone payment under the license agreement with Pfizer. The Letter Agreement permits the Company to make the milestone payment in installments with the remaining amount payable to Pfizer (including interest) to be made in September 2021 for approximately $21.9 million. Unpaid portions of the milestone payment will accrue interest at 6.25% per annum until paid. The installment payments and accrued interest are included in accrued in-licensed rights on the accompanying consolidated balance sheets.

The Company may trigger additional milestone payments in the future. Should the Company commercialize any more of the compounds licensed from Pfizer or any products containing any of these compounds, the Company will be obligated to pay to Pfizer annual royalties at a fixed rate in the low-to-mid teens of net sales of all such products, subject to certain reductions and offsets in some circumstances. The Company's royalty obligation continues, on a product-by-product and country-by-country basis, until the later of (1) the last to expire licensed patent covering the applicable licensed product in such country, or (2) the earlier of generic competition for such licensed product reaching a certain level in such country or expiration of a certain time period after first commercial sale of such licensed product in such country. In the event that the Company sublicenses the rights granted to the Company under the license agreement with Pfizer to a third party, the same milestone and royalty payments are required. The Company can terminate the license agreement at will, or for safety concerns, in each case upon specified advance notice.

Legal Proceedings

The Company and certain of its executive officers were named as defendants in the lawsuits detailed in Part II Item 1. "Legal Proceedings" of this Quarterly Report. The Company records a liability in the consolidated financial statements for loss contingencies when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required to estimate the amount and timing of a loss to be recorded.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the notes thereto included in Item 1 in this Quarterly Report on Form 10-Q, or this Quarterly Report. The following discussion should also be read in conjunction with our audited consolidated financial statements and the notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Unless otherwise provided in this Quarterly Report, references to the "Company," "we," "us," and "our" refer to Puma Biotechnology, Inc., a Delaware corporation, together with its wholly owned subsidiaries.

Overview

We are a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care. We in-license from Pfizer, Inc., or Pfizer, the global development and commercialization rights to PB272 (neratinib, oral), PB272 (neratinib, intravenous) and PB357. Neratinib is a potent irreversible tyrosine kinase inhibitor, or TKI, that blocks signal transduction through the human epidermal growth factor receptors, HER1, HER2 and HER4. Currently, we are primarily focused on the development and commercialization of the oral version of neratinib, and our most advanced drug candidates are directed at the treatment of HER2-positive breast cancer and HER2 mutated cancers. We believe neratinib has clinical application in the treatment of several other cancers as well, including other tumor types that over-express or have a mutation in HER2 or EGFR, such as breast cancer, cervical cancer, lung cancer or other solid tumors.

Prior to 2017, our efforts and resources had been focused primarily on acquiring and developing our pharmaceutical technologies, raising capital and recruiting personnel. In 2017, the U.S. Food and Drug Administration, or FDA, approved NERLYNX, formally known as PB272 (neratinib, oral), for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer following adjuvant trastuzumab-based therapy. In February 2020, NERLYNX was also approved by the FDA in combination with capecitabine for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting. In 2018, the European Commission, or EC, granted marketing authorization for NERLYNX in the European Union for the extended adjuvant treatment of adult patients with early stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab-based therapy.

We have entered into exclusive sub-license agreements with various parties to pursue regulatory approval, if necessary, and commercialize NERLYNX, if approved, in numerous regions outside the United States, including Europe (excluding Russia and Ukraine), Australia, Canada, China, Southeast Asia, Israel, Mexico, South Korea, and various countries and territories in Central and South America. We plan to continue to pursue commercialization of NERLYNX in other countries outside the United States, if approved.

During the three months ended March 31, 2021, we agreed to settle our ongoing arbitration proceeding with CANbridge BIOMED Limited, or CANbridge, relating to an agreement in which we granted CANbridge an exclusive sub-license to develop and commercialize NERLYNX throughout greater China. We and CANbridge agreed to drop our respective claims against one another. At the same time, we entered into a separate transaction in which we agreed to pay CANbridge a one-time termination fee of $20 million in exchange for it returning to us all rights to NERLYNX in greater China. Simultaneously with the recovery of such rights, we amended our existing sub-license agreement with Pierre Fabre Medicament SAS, or Pierre Fabre, to provide Pierre Fabre development, manufacturing and commercial rights to NERLYNX in greater China. The amendment provided that we would receive an upfront payment of $50 million and that we are eligible to receive additional regulatory and sales-based milestone payments that could add up to an additional $240 million. In addition, we are entitled to receive double-digit tiered royalties on the sales of NERLYNX in greater China.

Our expenses to date have been related to hiring staff, commencing company-sponsored clinical trials and the build out of our corporate infrastructure and, since 2017, the commercial launch of NERLYNX. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance product development. To date, our major sources of working capital have been proceeds from product and license revenue, public offerings of our common stock, proceeds from our credit facility and sales of our common stock in private placements.

Impact of COVID-19

Our priorities during the COVID-19 pandemic are protecting the health and safety of our employees while continuing our mission to develop and commercialize innovative products to enhance cancer care. Substantially all geographic regions in which our U.S. sales force operates have imposed, and those regions or other regions in which our sales force operates may in the future impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19. These types of restrictions may deter or prevent cancer patients from traveling to see their doctors and result in a decline in revenue for NERLYNX, our only commercial product. Additionally, our commercial team and sales force have limited travel and personal interactions with physicians and customers, including visits to healthcare provider offices due to limitations that have been imposed at certain hospitals and medical facilities, and are currently conducting a large percentage of promotional activities virtually. These types of restrictions have adversely impacted our ability to engage with our customers and have adversely impacted sales of NERLYNX, and they may continue to do so. The respective commercial teams of certain of the companies to which we sub-license the commercial rights to NERLYNX, and on which we rely for our international sales, have chosen or have been forced to take similar action, and other sub-licensees of NERLYNX may choose or be forced to take similar action. Furthermore, the COVID-19 pandemic has resulted in dramatic increases in unemployment rates, which may result in a substantial number of people becoming uninsured or underinsured. Any of these developments may have an adverse effect on our revenue. We have observed disruptions in patient enrollments in the United States and in our SUMMIT basket trial. If the COVID-19 pandemic continues to spread in the geographies in which we are conducting clinical trials, we may experience additional disruptions in those clinical trials, which could have a material adverse impact on our clinical trial plans and timelines.

Our ability to continue to operate without any significant negative impacts will in part depend on the length and severity of the COVID-19 pandemic and our ability to protect our employees and our supply chain. We continue to follow and monitor recommended actions of government and health authorities to protect our employees worldwide. For the three months ended March 31, 2021, we and our key third-party suppliers and manufacturers were able to broadly maintain operations. We rely exclusively on third-party manufacturers to manufacture NERLYNX.

We intend to satisfy our near-term liquidity requirements through a combination of our existing cash and cash equivalents and marketable securities as of March 31, 2021 and proceeds that will become available to us through product sales, royalties and sub-license milestone payments. However, this intention is based on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Some of these developments have had and may continue to have an adverse effect on our revenue and thus could have an adverse effect on our ability to satisfy the minimum revenue covenants in our loan and security agreement.

Critical Accounting Policies

As of the date of the filing of this Quarterly Report, we believe there have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2021 from our accounting policies at December 31, 2020, as reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020. We accounted for the following related to sub-license agreements during the three months ended March 31, 2021:

License Revenue:

We recognize license revenue under certain of our sub-license agreements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. We evaluate these agreements under ASC 606 to determine the distinct performance obligations. Non-refundable, up-front fees that are not contingent on any future performance and require no consequential continuing involvement by us, are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if the performance obligations are not satisfied.

Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration.

If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on its relative standalone selling price. The standalone selling price is generally determined based on the prices charged to customers or using expected cost-plus margin. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations.

Legal Contingencies and Expense:

For legal contingencies, we accrue a liability for an estimated loss if the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated. Legal fees and expenses are expensed as incurred based on invoices or estimates provided by legal counsel. We periodically evaluate available information, both internal and external, relative to such contingencies and adjust the accrual as necessary. We determine whether a contingency should be disclosed by assessing whether a material loss is deemed reasonably possible. In determining whether a loss should be accrued, we evaluate, among other factors, the degree of probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of the loss (see Note 13-Commitments and Contingencies in the accompanying notes to the financial statements).

Summary of Income and Expenses

Product revenue, net:

Product revenue, net consists of revenue from sales of NERLYNX. We sell NERLYNX to a limited number of specialty pharmacies and specialty distributors in the United States. We record revenue at the net sales price, which includes an estimate for variable consideration for which reserves are established. Variable consideration consists of trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates and other incentives.

License revenue:

License revenue consists of consideration earned for performance obligations satisfied pursuant to our sub-license agreements.

Royalty revenue:

Royalty revenue consists of consideration earned related to product sales made by our sub-licensees in their respective territories pursuant to our sub-license agreements.

Cost of sales:

Cost of sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NERLYNX. Cost of sales also includes period costs related to royalty charges payable to Pfizer, the amortization of milestone payments made to Pfizer, certain inventory manufacturing services, inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances.

Selling, general and administrative expenses:

Selling, general and administrative expenses, or SG&A Expenses, consist primarily of salaries and payroll-related costs, stock-based compensation expense, professional fees, business insurance, rent, general legal activities, credit loss expense and other corporate expenses. We expense SG&A Expenses as they are incurred.

Research and development expenses:

Research and development expenses, or R&D Expenses, include costs associated with services provided by consultants who conduct clinical services on our behalf, contract organizations for the manufacturing of clinical materials and clinical trials. During the three months ended March 31, 2021 and 2020, our R&D Expenses consisted primarily of clinical research organization, or CRO, fees; fees paid to consultants; salaries and related personnel costs; and stock-based compensation. We expense our R&D Expenses as they are incurred. Internal R&D Expenses primarily consist of payroll-related costs and also include equipment costs, travel expenses and supplies.

Results of Operations

Three Months Ended March 31, 2021 Compared to Three Months Ended March 31, 2020

Total revenue:

For the three months ended March 31, 2021, total revenue was approximately $98.2 million, compared to $51.2 million for the three months ended March 31, 2020.

Product revenue, net:

Product revenue, net was approximately $45.8 million for the three months ended March 31, 2021, compared to $48.6 million for the three months ended March 31, 2020. The decrease in product revenue, net was attributable to a volume decrease of approximately 20% in bottles of NERLYNX sold, and an increase in reserves for variable consideration from approximately 16% of product revenue for the three months ended March 31, 2020 to approximately 19% of product revenue for the three months ended March 31, 2021. The increase in reserves for variable consideration is primarily due to an increase in government rebates as a percentage of gross revenue. The decrease in product revenue, net was partially offset by an increase in gross selling price that occurred in the third quarter of 2020 and in the first quarter of 2021.

License revenue:

License revenue was approximately $50.0 million for the three months ended March 31, 2021, compared to approximately $2.0 million for the three months ended March 31, 2020. The increase in license revenue is due to a large, upfront payment in connection with an amendment to a sub-license agreement entered into during the three months ended March 31, 2021, compared to a smaller, milestone achievement reached during the three months ended March 31, 2020.

Royalty revenue:

Royalty revenue was approximately $2.4 million for the three months ended March 31, 2021, compared to $0.6 million for the three months ended March 31, 2020. The increase was due to increased product sales by our sub-licensees as they began to commercialize NERLYNX in additional territories.

Cost of sales:

Cost of sales was approximately $29.6 million for the three months ended March 31, 2021, compared to $9.1 million for the three months ended March 31, 2020. The increase in cost of sales was primarily attributable to a one-time license termination fee, an increase in the amortization of the intangible asset under our license agreement with Pfizer and increased royalty expense due to Pfizer related to the increase in royalty revenue, which was partially offset by decreased royalty expenses due to Pfizer related to the decrease in product revenue, net.

Selling, general and administrative expenses:

For the three months ended March 31, 2021, SG&A Expenses were approximately $28.2 million, compared to approximately $30.9 million for the three months ended March 31, 2020. SG&A Expenses for the three months ended March 31, 2021 and 2020 were as follows:

Selling, general, and administrative expenses (in thousands)	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2021	**2020**	**2021/2020**	**2021/2020**
Payroll and related costs	$ 10,511	$ 10,567	$ (56)	-0.5%
Professional fees and expenses	10,683	10,430	253	2.4%
Travel and meetings	1,012	2,416	(1,404)	-58.1%
Facilities and equipment costs	1,394	1,437	(43)	-3.0%
Stock-based compensation	3,601	4,692	(1,091)	-23.3%
Other	1,037	1,395	(358)	-25.7%
	$ 28,238	$ 30,937	$ (2,699)	-8.7%

For the three months ended March 31, 2021, SG&A Expenses decreased by approximately $2.7 million compared to the same period in 2020, primarily attributable to the following:

- a decrease in stock-based compensation expense of approximately $1.1 million primarily due to a decrease of approximately $2.0 million for stock awards that have fully vested and a decrease of approximately $0.7 million from stock awards forfeited, partially offset by an increase of approximately $1.6 million from new grants;
- a decrease in travel and meetings of approximately $1.4 million related to travel restrictions due to the COVID-19 pandemic; and
- a decrease in other expense of $0.4 million due to lower sponsorships, software, educational and training costs in the Commercial department.

These decreases were partially offset by:

- an increase in professional fees and expenses of approximately $0.3 million, consisting of an increase of approximately $1.1 million in legal related expenses and $0.1 million related to higher insurance premiums, partially offset by decreases of approximately $0.7 million in connection with consultants and contractors and $0.2 million in IT related costs.

Research and development expenses:

For the three months ended March 31, 2021, R&D expenses were approximately $20.2 million, compared to approximately $25.5 million for the three months ended March 31, 2020. R&D expenses for the three months ended March 31, 2021 and 2020 were as follows:

Research and development expenses (in thousands)	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2021	**2020**	**2021/2020**	**2021/2020**
Clinical trial expense	$ 6,126	$ 8,811	$ (2,685)	-30.5%
Internal R&D	10,260	10,229	31	0.3%
Consultant and contractors	1,583	2,200	(617)	-28.0%
Stock-based compensation	2,259	4,215	(1,956)	-46.4%
	$ 20,228	$ 25,455	$ (5,227)	-20.5%

For the three months ended March 31, 2021, R&D Expenses decreased approximately $5.2 million compared to the same period in 2020, primarily attributable to the following:

- a decrease in clinical trial expense of approximately $2.7 million, primarily due to the close out of NALA clinical trials and lower CRO expenses due to two studies nearing completion;
- a decrease in stock-based compensation expense of approximately $2.0 million, primarily due to a decrease of approximately $2.5 million for stock awards that fully vested and a decrease of approximately $0.3 million from stock award forfeitures, partially offset by an increase of approximately $0.9 million from new grants and other immaterial fluctuations; and
- a decrease in consultant and contractor expense of approximately $0.6 million, primarily due to the close out of NALA clinical trials and the use of fewer contractors and other immaterial fluctuations.

Other income (expenses):

Other income (expenses) (in thousands)	**For the Three Months Ended March 31,**		**Change**	
			$	**%**
	2021	**2020**	**2021/2020**	**2021/2020**
Interest income	$ 13	$ 386	$ (373)	-96.6%
Interest expense	(3,450)	(3,068)	(382)	12.5%
Legal verdict expense	(185)	(93)	(92)	98.9%
Other income	42	93	(51)	-54.8%
	$ (3,580)	$ (2,682)	$ (898)	33.5%

Interest income:

For the three months ended March 31, 2021, interest income decreased approximately $0.4 million compared to the three months ended March 31, 2020. The decrease in interest income reflects less cash invested in money market accounts and high-yield savings accounts in 2021 compared to 2020.

Interest expense:

For the three months ended March 31, 2021, we recognized approximately $3.5 million in interest expense, compared to $3.1 million of interest expense for the three months ended March 31, 2020. The increase in interest expense was primarily the result of the interest expense for the milestone payments being paid to Pfizer in installments.

Legal verdict expense:

For the quarter ended March 31, 2021, we recognized $0.2 million in legal verdict expense, which represents an estimate of service fees incurred related to the class action administrator and pre-judgment interest as a result of the *Hsu v. Puma Biotechnology, Inc., et al.* claims process and post-judgment interest for the *Eshelman v. Puma Biotechnology, Inc., et al.* judgment.

There was no material change in legal verdict expense compared to the quarter ended March 31, 2020.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2021 and December 31, 2020, and for the three months ended March 31, 2021 and 2020, and is intended to supplement the more detailed discussion that follows:

Liquidity and capital resources (in thousands)	As of March 31, 2021	As of December 31, 2020
Cash and cash equivalents	$ 95,653	$ 85,293
Marketable securities	$ 13,397	$ 8,096
Working capital	$ 23,357	$ 31,884
Stockholders' equity (deficit)	$ 16,437	$ (5,951)

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Cash provided by (used in):		
Operating activities	$ 15,661	$ (11,540)
Investing activities	(5,301)	34,377
Net increase in cash, cash equivalents and restricted cash	$ 10,360	$ 22,837

Operating Activities:

For the three months ended March 31, 2021, we reported net income of approximately $16.5 million, compared to a net loss of approximately $16.9 million for the same period in 2020. Additionally, cash provided by operating activities for the three months ended March 31, 2021 was approximately $15.7 million compared to approximately $11.5 million of cash used in operating activities for the same period in 2020.

Cash provided by operating activities for the three months ended March 31, 2021 consisted of net income of approximately $16.5 million, approximately $8.8 million of non-cash items, such as stock-based compensation and depreciation and amortization, and a decrease in other current assets of approximately $3.3 million; partially offset by a decrease in accrued expenses and other of approximately $6.6 million, an increase in inventory of approximately $4.3 million, a decrease in accounts payable of approximately $1.4 million and an increase in accounts receivable, net of approximately $0.6 million.

Cash used in operating activities for the three months ended March 31, 2020 consisted of a net loss of approximately $16.9 million, an increase in accounts receivable, net of approximately $2.6 million, an increase in prepaid expenses and other of approximately $1.1 million and a decrease in accounts payable of approximately $1.9 million; partially offset by approximately $10.8 million of non-cash items, such as stock-based compensation and depreciation and amortization, an increase in accrued expenses of approximately $0.4 million and other immaterial fluctuations.

Investing Activities:

During the three months ended March 31, 2021, cash used by investing activities was approximately $5.3 million, compared to net cash provided by investing activities of $34.4 million for the same period in 2020.

Cash used in investing activities during the three months ended March 31, 2021 consisted of approximately $10.7 million of available-for-sale securities, partially offset by maturities of approximately $5.4 million of available-for-sale securities.

Net cash provided by investing activities during the three months ended March 31, 2020 consisted of approximately $34.4 million of maturities of available-for-sale securities.

Financing Activities:

During the three months ended March 31, 2021, and the same period in 2020, cash was unchanged by financing activities.

Loan and Security Agreement:

In October 2017, we entered into a loan and security agreement with Silicon Valley Bank, or SVB, as administrative agent, and the lenders party thereto from time to time, or the Original Lenders, including Oxford Finance, LLC, or Oxford, and SVB. Pursuant to the terms of the credit facility provided for by the loan and security agreement, or the Original Credit Facility, we borrowed $50 million. In May 2018, we entered into an amendment to the loan and security agreement, which provided for an amended credit facility, or the Amended Credit Facility. Under the Amended Credit Facility, the Original Lenders agreed to make term loans available to us in an aggregate amount of $155 million, consisting of (i) an aggregate amount of $125 million, the proceeds of which, in part, were used to repay the $50 million we borrowed under the Original Credit Facility, and (ii) an aggregate amount of $30 million that we drew in December 2018, which was available under the Amended Credit Facility as a result of achieving a specified minimum revenue milestone.

On June 28, 2019, or the Effective Date, we entered into an amendment and restatement of the loan and security agreement, which provided for a new credit facility, or the New Credit Facility, with Oxford, as collateral agent, and the lenders party thereto from time to time, including Oxford, pursuant to which we repaid the $155.0 million outstanding under the Amended Credit Facility, as well as all applicable exit and prepayment fees, owed to the Original Lenders under the Amended Credit Facility, using cash on hand and $100.0 million in new borrowings from the New Credit Facility. Under the New Credit Facility, we issued to Oxford new and/or replacement secured promissory notes in an aggregate principal amount for all such promissory notes of $100.0 million evidencing the New Credit Facility. No additional money remains available to us under the New Credit Facility.

The New Credit Facility is secured by substantially all of our personal property other than our intellectual property. We also pledged 65% of the issued and outstanding capital stock of our subsidiaries, Puma Biotechnology Ltd. and Puma Biotechnology B.V. The New Credit Facility limits our ability to grant any interest in our intellectual property to certain permitted licenses and permitted encumbrances set forth in the agreement.

The term loans under the New Credit Facility bear interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. We are required to make monthly interest-only payments on each term loan under the New Credit Facility commencing on the first calendar day of the calendar month following the funding date of such term loan, and continuing on the first calendar day of each calendar month thereafter through August 1, 2021, or the Amortization Date. Commencing on the Amortization Date, and continuing on the first calendar day of each calendar month thereafter, we will make consecutive equal monthly payments of principal, together with applicable interest, in arrears to each lender under the New Credit Facility, calculated pursuant to the New Credit Facility. All unpaid principal and accrued and unpaid interest with respect to each term loan under the New Credit Facility is due and payable in full on June 1, 2024, or the Maturity Date. Upon repayment of such term loans, we are also required to make a final payment to the lenders equal to 7.5% of the aggregate principal amount of such term loans outstanding as of the Effective Date. The effective interest rate as of March 31, 2021 was 12.75%.

At our option, we may prepay the outstanding principal balance of any term loan in whole but not in part, subject to a prepayment fee of 3.0% of any amount prepaid if the prepayment occurs through and including the first anniversary of the funding date of such term loan, 2.0% of the amount prepaid if the prepayment occurs after the first anniversary of the funding date of such term loan through and including the second anniversary of the funding date of such term loan, and 1.0% of the amount prepaid if the prepayment occurs after the second anniversary of the funding date of such term loan and prior to the Maturity Date.

The New Credit Facility includes affirmative and negative covenants applicable to us, our current subsidiaries and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. We must also achieve certain product revenue targets, measured as of the last day of each fiscal quarter on a trailing year-to-date basis. New minimum revenue levels will be established for each subsequent fiscal year by mutual agreement of us, Oxford, as collateral agent, and the lenders under the New Credit Facility. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets and suffering a change in control, in each case subject to certain exceptions.

The New Credit Facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the New Credit Facility, including foreclosure against the property securing the New Credit Facility, including our cash. These events of default include, among other things, our failure to pay principal or interest due under the New Credit Facility, a breach of certain covenants under the New Credit Facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $500,000 and one or more judgments against us in an amount greater than $500,000 individually or in the aggregate that remains unsatisfied, unvacated, or unstayed for a period of 10 days after its entry.

On February 27, 2020, we entered into an amendment of the New Credit Facility with Oxford to establish our minimum revenue thresholds for the trailing year to date periods ending March 31, June 30, September 30, and December 31, 2020 and the fiscal year 2021. On August 5, 2020, we entered into an amendment of the New Credit Facility with Oxford to amend the minimum revenue thresholds for the trailing year to date periods ending September 30 and December 31, 2020. On February 3, 2021, we entered into an amendment of the New Credit Facility with Oxford to establish our minimum revenue thresholds for the trailing year to date periods ending March 31, June 30, September 30 and December 31, 2021.

As of March 31, 2021, there were $100.0 million in term loans outstanding under the New Credit Facility, representing all of our long-term debt outstanding as of that date, and we were in compliance with all applicable covenants under the New Credit Facility.

Current and Future Financing Needs:

We did not receive or record any product revenues until the third quarter of 2017. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, our research and development efforts and our commercialization efforts.

We may choose to begin new research and development efforts or we may choose to launch additional marketing efforts. These efforts may require funding in addition to the cash and cash equivalents totaling approximately $95.7 million and $13.4 million in marketable securities available at March 31, 2021. While our consolidated financial statements have been prepared on a going concern basis, we expect to continue incurring significant losses for the foreseeable future and will need to generate significant revenue to sustain operations and successfully commercialize neratinib. While we have been successful in raising financing in the past, there can be no assurance that we will be able to do so in the future. Our ability to obtain funding may be adversely impacted by uncertain market conditions, including on account of the global COVID-19 pandemic, our success in commercializing neratinib, unfavorable decisions of regulatory authorities or adverse clinical trial results. The outcome of these matters cannot be predicted at this time.

In addition, we have based our estimate of capital needs on assumptions that may prove to be wrong. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities, the impact of commercialization efforts, acquisitions of additional drug candidates and changes in regulation. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources of funds. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs, and the opportunities presented by such programs, and allocate our resources in the manner most prudent.

Non-GAAP Financial Measures

In addition to our operating results, as calculated in accordance with generally accepted accounting principles, or GAAP, we use certain non-GAAP financial measures when planning, monitoring, and evaluating our operational performance. The following table presents our net loss and net loss per share, as calculated in accordance with GAAP, as adjusted to remove the impact of stock-based compensation. For the three months ended March 31, 2021, stock-based compensation represented approximately 12.1% of our operating expenses, compared to 15.8% for the same period in 2020, in each case excluding cost of sales. Our management believes that these non-GAAP financial measures are useful to enhance understanding of our financial performance, are more indicative of our operational performance and facilitate a better comparison among fiscal periods. These non-GAAP financial measures are not, and should not be viewed as, substitutes for GAAP reporting measures.

Reconciliation of GAAP Net Income (Loss) to Non-GAAP Adjusted Net Income (Loss) and GAAP Net Income (Loss) Per Share to Non-GAAP Adjusted Net Income (Loss) Per Share (in thousands except share and per share data)

	For the Three Months Ended March 31,			
	2021		2020	
GAAP net income (loss)	$ 16,528		$ (16,933)	
Adjustments:				
Stock-based compensation -				
Selling, general and administrative	3,601		4,692	(1)
Research and development	2,259		4,215	(2)
Non-GAAP adjusted net income (loss)	$ 22,388		$ (8,026)	
GAAP net income (loss) per share—basic	$ 0.41		$ (0.43)	
Adjustment to net income (loss) (as detailed above)	0.15		0.23	
Non-GAAP adjusted basic net income (loss) per share	$ 0.56	(3)	$ (0.20)	(3)
GAAP net income (loss) per share—diluted	$ 0.40		$ (0.43)	
Adjustment to net income (loss) (as detailed above)	0.15		0.23	
Non-GAAP adjusted diluted net income (loss) per share	$ 0.55	(4)	$ (0.20)	(5)

(1) To reflect a non-cash charge to operating expense for selling, general, and administrative stock-based compensation.
(2) To reflect a non-cash charge to operating expense for research and development stock-based compensation.
(3) Non-GAAP adjusted basic net income (loss) per share was calculated based on 40,260,864 and 39,291,162 weighted-average shares of common stock outstanding for the three months ended March 31, 2021 and 2020, respectively.
(4) Non-GAAP adjusted diluted net income per share was calculated based on 40,894,868 weighted-average shares of common stock outstanding for the three months ended March 31, 2021.
(5) Potentially dilutive common stock equivalents (stock options, restricted stock units and warrants) were not included in this non-GAAP adjusted diluted net loss per share for the three months ended March 31, 2020, as these shares would be considered anti-dilutive.

Off-Balance Sheet Arrangements

We do not have any “off-balance sheet agreements,” as defined by SEC regulations.

Contractual Obligations

In June 2020, we entered into a letter agreement, or the Letter Agreement, with Pfizer relating to the method of payment associated with our achievement of a milestone that triggered a $40 million payment under our license agreement with Pfizer. The Letter Agreement permits us to make the milestone payment in installments with the majority of the amount payable to Pfizer (including interest) to be made in 2021 and the final payment occurring by September 30, 2021. Unpaid portions of the milestone payment will accrue interest at 6.25% per annum until paid.

Other than as described in the preceding paragraph, there have been no material changes outside the ordinary course of business to our contractual obligations and commitments as described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the cash equivalents to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. We invested our excess cash primarily in cash equivalents such as money market investments as of March 31, 2021. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Because of the short-term maturities of our cash equivalents, we do not believe that a 10% increase in interest rates would have a material effect on the realized value of our cash equivalents.

We also have interest rate exposure as a result of borrowings outstanding under our loan and security agreement. As of March 31, 2021, the outstanding principal amount of our borrowings was $100.0 million. Our borrowings under the loan and security agreement, as amended, bear interest at an annual rate equal to the greater of (i) 9.0% and (ii) the sum of (a) the "prime rate," as reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.5%. Changes in the prime rate may therefore affect our interest expense associated with our borrowings under the loan and security agreement.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rule 13a-15(e)), as of March 31, 2021. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures were effective as of March 31, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2021 have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Hsu v. Puma Biotechnology, Inc., et al.

On June 3, 2015, Hsingching Hsu, individually and on behalf of all others similarly situated, filed a class action lawsuit against us and certain of our executive officers in the United States District Court for the Central District of California (Case No. 8:15-cv-00865-AG-JCG). On October 16, 2015, lead plaintiff Norfolk Pension Fund filed a consolidated complaint on behalf of all persons who purchased our securities between July 22, 2014 and May 29, 2015. A trial on the claims relating to four statements alleged to have been false or misleading was held from January 15 to January 29, 2019. At trial, the jury found that three of the four challenged statements were not false or misleading, and thus found in the defendants' favor on those claims. The jury found liability as to one statement and awarded a maximum of $4.50 per share in damages, which represents approximately 5% of the total claimed damages of $87.20 per share. On September 9, 2019, the Court entered an order specifying the rate of prejudgment interest to be awarded on any valid claims at the 52-week Treasury Bill rate. On September 8, 2020, the claims administrator submitted its final claims report to the Court and, on October 9, 2020, the claims administrator submitted its supplemental claims report. The claims report reflects approximately $50.5 million in claimed damages. We disagree with the amount of claimed damages. On November 27, 2020, the Court issued an order setting out the process for challenging claims. Based on a review of specific claims and subject to the outcome of the claims challenge process, we believe that total claimed damages after all claims challenges have been adjudicated could range from $24.9 million to $51.4 million. The total amount of aggregate class-wide damages still remains uncertain and will be ascertained only after the claims challenge process and the exhaustion of any appeals. It is reasonably possible that the final total damages awarded will differ from these estimates; however, the amount is not estimable at this time. A final judgment has not been entered.

Eshelman v. Puma Biotechnology, Inc., et al.

In February 2016, Fredric N. Eshelman filed a lawsuit against our Chief Executive Officer and President, Alan H. Auerbach, and us in the United States District Court for the Eastern District of North Carolina (Case No. 7:16-cv-00018-D). The complaint generally alleged that we and Mr. Auerbach made defamatory statements regarding Dr. Eshelman in connection with a proxy contest. In May 2016, Dr. Eshelman filed a notice of voluntary dismissal of the claims against Mr. Auerbach. A trial on the remaining defamation claims against us took place from March 11 to March 15, 2019. At trial, the jury found us liable and awarded Dr. Eshelman $15.9 million in compensatory damages and $6.5 million in punitive damages. We strongly disagree with the verdict and, on April 22, 2019, filed a motion for a new trial or, in the alternative, a reduced damages award. The Court denied that motion on March 2, 2020. We have appealed that ruling and the verdict. Additionally, after trial, the plaintiff filed a motion seeking approximately $3 million in attorneys' fees, as well as pre-judgment interest. In the Court's March 2 ruling, it denied the motion for attorneys' fees but granted the request for pre-judgment interest, bringing the total judgment to $26.3 million. On March 30, 2020, the plaintiff filed a notice of cross-appeal and conditional cross-appeal, appealing the Court's order denying the plaintiff's request for attorneys' fees and conditionally cross-appealing a Court ruling that certain communications between Mr. Auerbach and his attorneys were protected by attorney-client privilege and a related evidentiary ruling. We estimate the high end of potential damages in the matter could be approximately $27.9 million; however, the actual amount of damages payable by us is still uncertain and will be ascertained only after completion of the appeal and any subsequent proceeding, and such amount could be greater than the amount of expense already recognized or the high end of the estimate. The United States Court of Appeals for the Fourth Circuit heard oral argument in our appeal on May 4, 2021.

CANbridge Licensing Dispute

On July 28, 2020, we filed a request for arbitration against CANbridge BIOMED Limited, or CANbridge, before the ICC International Court of Arbitration. We asserted that CANbridge violated the terms of our agreement with CANbridge in which we granted CANbridge an exclusive sublicense to develop and commercialize NERLYNX throughout greater China. We sought an arbitral award, as well as damages, costs, and attorneys' fees. On August 26, 2020, CANbridge filed its response to our request for arbitration and brought counterclaims, seeking damages, costs and attorneys' fees. On February 24, 2021, we and CANbridge resolved our dispute, with each side agreeing to dismiss our respective claims in the arbitration. The settlement is limited to claims asserted in the arbitration, or that are related to the claims asserted in the arbitration.

Legal Malpractice Suit

On September 17, 2020, we filed a lawsuit against Hedrick Gardner Kincheloe & Garofalo, L.L.P. and David L. Levy, the attorneys who previously represented us in *Eshelman v. Puma Biotechnology, Inc., et al.* in the Superior Court of Mecklenburg County, North Carolina. We are alleging legal malpractice based on the defendants' negligent handling of the defense of us in *Eshelman v. Puma Biotechnology, Inc., et al*. as detailed above. We are seeking recovery of the entire amount awarded in *Eshelman v. Puma Biotechnology, Inc., et al.* On November 23, 2020, the defendant filed an answer to the complaint denying the allegations of negligence.

Item 1A. RISK FACTORS

Under Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020, we identified important factors that could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report. There has been no material change in our risk factors subsequent to the filing of our prior reports referenced above. However, the risks described in our reports are not the only risks we face. Additional risks and uncertainties that we currently deem to be immaterial or not currently known to us, as well as other risks reported from time to time in our reports to the SEC, also could cause our actual results to differ materially from our anticipated results or other expectations.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

We did not sell any of our equity securities without registration under the Securities Act of 1933, as amended, during the three months ended March 31, 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Neither we nor any "affiliated purchasers" within the definition of Rule 10b-18(a)(3) promulgated under the Exchange Act made any purchases of our equity securities during the quarter ended March 31, 2021.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

Item 6. EXHIBITS

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 14, 2016 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 15, 2016 and incorporated herein by reference)
3.2	Third Amended and Restated Bylaws of the Company (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 28, 2019 and incorporated herein by reference)
10.1+*	Fourth Amendment to Amended and Restated Loan and Security Agreement, dated February 3, 2021, by and between the Company and Oxford Finance LLC, as collateral agent and Lender
10.2+*	Termination Agreement, dated February 24, 2021, by and between the Company and CANbridge BIOMED Limited
10.3+*	Amendment No. 3 to the License Agreement, dated February 24, 2021, by and between the Company and Pierre Fabre Medicament SAS
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021
32.1++	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	Inline XBRL Instance Document
101.SCH+	Inline XBRL Taxonomy Extension Schema Document
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	Inline XBRL Taxonomy Extension Linkbase Document
104+	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\+ Filed herewith

++ Furnished herewith

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Regulation S-K, Item 601(b)(10). Such omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed. Additionally, certain schedules and attachments to certain of these exhibits have been omitted pursuant to Regulation S-K, Item 601(a)(5).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PUMA BIOTECHNOLOGY, INC.

Date: May 6, 2021

By: /s/ Alan H. Auerbach
Alan H. Auerbach
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 6, 2021

By: /s/ Maximo F. Nougues
Maximo Nougues
Chief Financial Officer
(Principal Financial and Accounting Officer)

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

FOURTH AMENDMENT TO AMENDED AND RESTATED LOAN AND SECURITY AGREEMENT

THIS **FOURTH AMENDMENT** to Amended and Restated Loan and Security Agreement (this "**Amendment**") is entered into as of February 3, 2021, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time (including Oxford in its capacity as a Lender) (each a "**Lender**" and collectively, the "**Lenders**"), and **PUMA BIOTECHNOLOGY, INC.**, a Delaware corporation with offices located at 10880 Wilshire Blvd., Ste. 2150, Los Angeles, CA 90024 ("**Borrower**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Amended and Restated Loan and Security Agreement dated as of June 8, 2019 (as amended by that certain First Amendment to Amended and Restated Loan and Security Agreement dated as of February 27, 2020, as amended by that certain Second Amendment to Amended and Restated Loan and Security Agreement dated as of July 6, 2020, as amended by that certain Third Amendment to Amended and Restated Loan and Security Agreement dated as of August 5, 2020, and as may be further amended from time to time, the "**Loan Agreement**").

B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.

C. Borrower has requested that Collateral Agent and Lenders (i) amend the minimum revenue covenant for the fiscal year ending December 31, 2021 and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.

D. Collateral Agent and Lenders have agreed to amend certain provisions of the Loan Agreement, but only to the extent and subject to the terms and conditions, and in reliance upon the representations and warranties, set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Amendment to Loan Agreement.

2.1 Section 6.10 (Minimum Revenue). Section 6.10 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**6.10 Minimum Revenue.** Borrower shall achieve net commercial revenues (inclusive of commercial product sales and royalties from commercial product sales, but, for the sake of clarity, exclusive of upfront or milestone payments from licensing agreements), measured in accordance with GAAP as of the last day of each fiscal quarter on a trailing year to date basis greater than or equal to the amounts set forth below.

Fiscal Quarter Ending	Minimum Revenue
March 31, 2021	[***]
June 30, 2021	[***]
September 30, 2021	[***]
December 31, 2021	[***]

New minimum revenue levels for each fiscal quarter following the fiscal year ending December 31, 2021 and each fiscal year thereafter shall be set by the mutual agreement of Borrower, Collateral Agent and the Lenders, such new minimum revenue levels to show year over year revenue growth and based on the projections delivered by Borrower to Collateral Agent and the Lenders pursuant to Section 6.2(a)(iii) hereof, and pursuant to an amendment to this Agreement which Borrower hereby agrees to execute no later than February 28th of each year. Such revenue projections shall be acceptable to Collateral Agent and the Lenders in their sole but reasonable discretion and in any case shall show year over year revenue growth (at a rate to be reasonably agreed) and it shall be an immediate Event of Default if Borrower, Collateral Agent and the Lenders (in each case acting reasonably) fail to enter into the aforementioned amendment on or prior to February 28th of each year."

2.2 **Section 10 (Notices)**. Section 10 of the Loan Agreement is hereby amended by replacing the notice information for Collateral Agent with the following:

"If to Collateral Agent: OXFORD FINANCE LLC
115 South Union Street
Suite 300
Alexandria, VA 22314
Attention: Legal Department
Fax: (703) 519-5225
Email: LegalDepartment@oxfordfinance.com

with a copy (which shall not constitute notice) to:

DLA Piper LLP (US)
500 8th Street, NW
Washington, DC 20004
Attention: Eric Eisenberg
Fax: (202) 799-5211
Email: eric.eisenberg@dlapiper.com"

3. Limitation of Amendment.

3.1 The amendment set forth in **Section 2**, is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof ; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

4.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders prior to the date hereof, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

4.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;

4.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;

4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; (in each case, except as already have been obtained and are in full force and effect); and

4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

5. Release.

5.1 The Borrower hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent ("**Releasees**"), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof and through the date hereof. Without limiting the generality of the foregoing, the Borrower waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan

Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof. In furtherance of this release, Borrower expressly acknowledges and waives any and all rights under Section 1542 of the California Civil Code, which provides as follows:

> "**A GENERAL RELEASE** DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY." (Emphasis added.)

6. Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

7. Effectiveness. This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of this Amendment by each party hereto.

[*Balance of Page Intentionally Left Blank*]

In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

BORROWER:

PUMA BIOTECHNOLOGY, INC.

By: /s/ Maximo Nougues
Name: Maximo Nougues
Title: Chief Financial Officer

[*Signature Page to Fourth Amendment to Amended and Restated Loan and Security Agreement*]

Exhibit 10.2

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

TERMINATION AGREEMENT

This TERMINATION AGREEMENT (this "**Agreement**") is made and entered into effective as of February 24, 2021 (the "**Effective Date**"), by and between CANbridge BIOMED Limited, a corporation organized and existing under the laws of Hong Kong ("**CANbridge**"), and PUMA Biotechnology, Inc., a corporation organized and existing under the laws of Delaware, USA ("**PUMA**"), in the presence of Pierre Fabre Medicament SAS, a company duly organized and existing under the laws of France, having offices and principal place of business at 45 Place Abel Gance, 92100 Boulogne, France ("**PFM**"). CANbridge and PUMA are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, CANbridgepharma Limited, a corporation organized and existing under the laws of Hong Kong, and PUMA entered into a Collaboration and License Agreement dated January 30, 2018 (the "**License Agreement**");

WHEREAS, CANbridgepharma Limited assigned its interest under the License Agreement to CANbridge on or around July 23, 2018;

WHEREAS, the Parties mutually wish to terminate the License Agreement and any and all agreements and documents that relate to the License Agreement, including without limitation the Supply Agreement between the Parties dated as of August 22, 2019 (the "**Supply Agreement**"), the Quality and Technical Agreement between the Parties dated as of November 11, 2019 (the "**Quality Agreement**"), and the Safety Data Exchange Agreement between the Parties dated as of December 9, 2019 (the "**Safety Data Agreement**"), in each case, in each of their entirety as of the Effective Date, except as specifically set forth herein;

WHEREAS, in connection with termination of the License Agreement, Supply Agreement, Quality Agreement, Safety Data Agreement, and any and all other agreements and documents related thereto, CANbridge agrees to assign or transfer certain rights and assets to PUMA in connection therewith as set forth herein;

WHEREAS, PUMA and PFM entered into a license agreement dated March 29, 2019, as amended from time to time ("**PFM License Agreement**");

WHEREAS, as of the Effective Date, PUMA and PFM are amending the PFM License Agreement to include the People's Republic of China, including mainland China, Hong Kong, Macao and Taiwan, as part of the territory licensed to PFM under the PFM License Agreement;

WHEREAS, PFM is a third party beneficiary of certain rights provided under this Agreement, including the right to enforce certain obligations of CANbridge;

WHEREAS, as of the Effective Date, CANbridge and PFM are entering into the Ancillary Agreements to implement the transfer of certain items and rights previously held by CANbridge under the License Agreement and other agreements referenced above; and

WHEREAS, as of the Effective Date, PUMA and CANbridge are entering into a Settlement Agreement to settle certain disputes that have arisen between the parties related to the License Agreement.

NOW THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows.

1. DEFINITIONS

Capitalized terms not otherwise defined herein shall have the meanings ascribed to them under the License Agreement.

1.1 "**Affiliate**" has the meaning set forth in the License Agreement, provided, however, that for purposes of Section 4.12(d), "Affiliate" shall not include [***].

1.2 "**Ancillary Agreements**" means the Distribution Agreement and the Transition Services Agreement, and the quality agreement and the safety data exchange agreement contemplated therein.

1.3 "**Designee**" shall mean PFM or any of its Affiliates.

1.4 "**Distribution Agreement**" means the Distribution Agreement between CANbridge and a Designee dated as of the Effective Date.

1.5 "**Personal Data**" means any information that, pursuant to applicable Law (a) relates to an identified or identifiable natural person that is subject to access, collection, use, storage, processing, or disclosure restrictions, or (b) requires notification to a Person if such information is lost, misused, or wrongfully accessed.

1.6 "**Transition Services Agreement**" or "**TSA**" means the Transition Services Agreement between CANbridge and a Designee dated as of the Effective Date.

2. TERMINATION; EFFECT OF TERMINATION; SURVIVAL.

2.1 **Termination**. Subject to the terms of this Agreement, the Parties agree that the agreements, documents, letters, authorizations, certificates and all items listed under **Schedule 2.1** shall terminate, in each case, in each of their entirety effective as of the Effective Date (the "**Terminated Agreements and Documents**"). For clarity, this Agreement shall serve as PUMA's or its sublicensees' or contractors' written notice to terminate PUMA's or its sublicensees' or contractors' grant of all confirmatory letters, letters of authorization and powers of attorney granted to CANbridge, its Affiliates or Sublicensees, or each of its or their officers, directors, employees, agents, contractors or designees, whether written or oral, existing immediately prior to the Effective Date, effective as of the Effective Date.

2.2 **Effects of Termination Generally**. Subject to the terms of this Agreement, including Section 2.3, the Parties' rights and obligations under the Terminated Agreements and Documents shall terminate as of the Effective Date, and neither Party will have any further rights or obligations under the Terminated Agreements and Documents from and after the Effective Date.

2.3 **Survival**. Notwithstanding the foregoing, and anything to the contrary herein:

(a) the following provisions of the License Agreement shall continue to survive and CANbridge's and its Affiliates' activities performed under this Agreement and each of the Ancillary Agreements shall be subject to such provisions, so long as (i) CANbridge's Affiliate remains PUMA's "local agent" for the purposes of the Marketing Authorization of the Licensed Product granted by the National Medical Products Administration ("**NMPA**") of mainland China and (ii) CANbridge's Affiliate remains the Marketing Authorization holder of the Marketing Authorization granted by the Taiwan Food and Drug Administration of Taiwan and the Pharmacy and Poisons Board of Hong Kong, in each case, that references PUMA's

Marketing Authorization approved by the FDA: Article 1 (Definitions), the last sentence of Section 3.4.2 (Regulatory Communications), Section 3.4.5 (Regulatory Investigation or Inquiry) and Section 4.2.5 (Diversion), provided, however, in the event of conflict between any provisions of the License Agreement and this Agreement, the terms of this Agreement shall control solely with respect to provisions related to communications with Regulatory Authorities in the Territory, and for all other such conflicting provisions, the provisions of the License Agreement shall control, provided, further, the term "this Agreement" as used in the License Agreement shall include the License Agreement and this Agreement for the purposes of this Section 2.3(a).

(b) the terms of the Supply Agreement, Quality Agreement and the Safety Data Agreement shall continue to survive with respect to (i) any and all Licensed Products supplied by PUMA to CANbridge or any of its Affiliates or designees prior to the Effective Date and (ii) any Licensed Products supplied by PUMA to CANbridge or any of its Affiliates of designees prior to the amendment of the supply agreement between PUMA and PFM (which amendment, for clarity, will contain provisions pursuant to which PUMA will agree to supply PFM, its Affiliates and/or its distributors, including CANbridge, and PFM will agree to receive and purchase, the Licensed Products from PUMA in accordance with the terms therein) (any such Licensed Products supplied by PUMA to CANbridge in accordance with this Section 2.3(b), "**CANbridge Licensed Products**"), provided, that (1) the term (A) "this Agreement" as used in the Supply Agreement shall include the Supply Agreement and this Agreement, (B) "QTA" as used in the Quality Agreement shall include the Quality Agreement and this Agreement, and (C) "the Agreement" as used in the Safety Data Agreement shall include the Safety Data Agreement and this Agreement, in each case, for the purposes of this Section 2.3(b); and (2) PUMA shall provide prompt written notice to CANbridge following effectiveness of any supply agreement entered into between PUMA and a Designee following the date hereof;

(c) the following provisions of the License Agreement shall continue to survive so long as CANbridge or any of its Affiliates or contractors have title to any CANbridge Licensed Products: Section 4.2.2 (Commercialization Responsibilities), Section 4.2.5 (Diversion), Section 4.2.6 (No Violation), Section 6.1.2(b) (Sales Milestone Payments), Section 6.1.3 (Milestone Event Notice), Section 6.2 (Royalties), Section 6.3 (Royalty Payments and Reports), Section 6.5 (Financial Audits), Section 6.6 (Tax Matters), Section 6.7 (Currency of Payments), Section 6.8 (Blocked Currency), Section 6.9 (Late Payments), provided, the term "this Agreement" as used in the License Agreement shall include the License Agreement and this Agreement for the purposes of this Section 2.3(c); and

(d) the following provisions of the License Agreement shall continue to survive the termination of the License Agreement: Sections 2.1.3, 3.3.1 (until the earlier of (a) [***] following the Effective Date, or (b) otherwise agreed under the Ancillary Agreements), 7.1, 7.2 (solely with respect to Joint Patent Rights), Article 8 (Confidentiality), Article 10 (Indemnification; Damages), Article 11 (Limitation of Liability), Article 13 (Dispute Resolution), and Article 14 (Miscellaneous); provided, however, in the event of conflict between any provisions of the License Agreement and this Agreement, the terms of this Agreement shall control, provided, further, the term "this Agreement" as used in the License Agreement shall include the License Agreement and this Agreement for the purposes of this Section 2.3(d); provided, further, [***].

(e) the following provisions of the Supply Agreement shall continue to survive the termination of the Supply Agreement: Article 1, Article 6, Article 8.3 and Article 10.

(f) the following provisions of the Quality Agreement shall continue to survive the termination of the Quality Agreement: Article 22.

(g) the following provisions of the Safety and Data Agreement shall continue to survive the termination of the Safety and Data Agreement: Article 14.

3. PAYMENT

3.1 No later than [***] business days in France and in the US following the Effective Date, PUMA will pay CANbridge a termination fee of Twenty Million Dollars ($20,000,000).

4. POST-TERMINATION

4.1 **Ancillary Agreements**. In consideration for the amounts received by CANbridge from PUMA under this Agreement, CANbridge, as of the Effective Date, has entered into the Ancillary Agreements with one or more Designees to implement a smooth and efficient transition from CANbridge to such Designee(s) of the ongoing activities with respect to the Licensed Products in the Territory. CANbridge shall provide all the services required to be provided by CANbridge thereunder in accordance with the terms of the Ancillary Agreements. To enable CANbridge and such Designees to implement such transition and to perform such ongoing activities with respect to the Licensed Products in the Territory in accordance with the terms of this Agreement and each of the Ancillary Agreements, PUMA will provide all reasonably necessary assistance to such Designees, including by providing written letters of authorization and powers of attorney to establish the required authority with the respective Governmental Authorities to carry out the intent of this Agreement and the Ancillary Agreements.

4.2 **Access**.

(a) CANbridge shall, and shall cause its Affiliates to, grant PUMA or a Designee specified in writing by PUMA, and any representatives of such Designee, continued reasonable access upon reasonable prior notice, to CANbridge and its Affiliates' books and records to the extent such books and records primarily relate to the Exploitation of the Licensed Products in the Territory for the sole purposes of enabling PUMA's or such Designee's transition of the Exploitation of the Licensed Products in the Territory for a period of [***] years from the Effective Date or such other longer period as set forth in any of the Ancillary Agreements. Such access may be granted through electronic virtual data rooms, and to the extent physically accessible, such access shall be granted during normal business hours; provided, however, that such access shall not unreasonably disrupt CANbridge's ordinary course operations.

(b) Prior to making any books and records available to PUMA or a Designee in accordance with Section 4.2(a), CANbridge or its Affiliates may redact any information to the extent that (i) such information do not primarily relate to the Exploitation of the Licensed Products in the Territory or (ii) providing such books and records available to PUMA or a Designee would jeopardize any legal privilege belonging to CANbridge or its Affiliates; provided, however, that, notwithstanding the foregoing, CANbridge shall not have the right to redact information from the Regulatory Filings of any of the Licensed Products that are required to Exploit the Licensed Products in the Territory.

4.3 **Inventory and Stock; Promotional Materials.**

(a) **Inventory and Stock**. CANbridge shall, or shall cause its Affiliates or its designee to handle the inventory and stock of Licensed Products owned by CANbridge or any of its Affiliates in the Territory as of the Effective Date in accordance with the Ancillary Agreements, and subject to the terms of the Supply Agreement, the Quality Agreement and the Safety Data Agreement.

(b) **Promotional Materials**. Within [***] days from the Effective Date, CANbridge shall, or shall cause its Affiliates to (i) destroy any and all promotional materials related to the Licensed

Products owned by CANbridge or any of its Affiliates, (ii) transfer such promotional materials to PUMA or a Designee or (iii) retain them for use in accordance with the Ancillary Agreements.

4.4 **Transfer of Regulatory Filings and Marketing Authorizations; Termination of Local Agent**.

(a) **General**. In accordance with and subject to the terms of this Agreement, including Sections 4.4(b), 4.4(c), and 4.4(d), and any applicable provisions under the Ancillary Agreements, CANbridge shall, or shall cause its Affiliates to, unless prohibited by applicable Law, and [***], assign and transfer to PUMA or a Designee specified in writing by PUMA all Regulatory Filings, filings for Pricing and Reimbursement Approval, and Marketing Authorizations, in each case, that are held by or under authority and control of CANbridge or its Affiliates in connection with the Licensed Products in the Territory as of the Effective Date. CANbridge shall, and shall cause its Affiliates to, take any and all actions and to execute all instruments, assignments and documents as may be necessary to effect the transfer of rights as contemplated under this Section 4.4. If applicable Law or relevant Regulatory Authorities prevent or delay such transfer of ownership of any such Regulatory Filing, filing for Pricing and Reimbursement Approval and/or Marketing Authorizations to PUMA or a Designee specified in writing by PUMA, then CANbridge will grant, and hereby does grant, to PUMA and its Designee specified in writing by PUMA an exclusive and irrevocable right of access and right of reference to such Regulatory Filing, filing for Pricing and Reimbursement Approval and Marketing Authorizations for Licensed Products in the Territory, and will reasonably cooperate with PUMA or a Designee specified in writing by PUMA, at CANbridge's expense, to make the benefits of such Regulatory Filings, filings for Pricing and Reimbursement Approval and Marketing Authorizations available to PUMA or a Designee(s).

(b) **Mainland China**. As of the Effective Date, in mainland China, (i) the applicable Regulatory Authorities have issued the Marketing Authorization for the Licensed Product to PUMA, (ii) PUMA is the registered Marketing Authorization holder of the Licensed Product and (iii) CANbridge's Affiliate is acting as PUMA's "local agent" for the Licensed Product. As soon as practicable after the Effective Date and unless otherwise provided in one or more Ancillary Agreements, PUMA and CANbridge shall, in coordination with a Designee specified in writing by PUMA, promptly remove the respective CANbridge Affiliate as PUMA's "local agent" for the Licensed Products and appoint Pierre Fabre Medicament China as the new "local agent" of PUMA in accordance with the terms of the TSA ("**Local Agent Replacement**") in mainland China. From the Effective Date until the effective date of the applicable Local Agent Replacement pursuant this Section 4.4(b), CANbridge shall, and shall cause its Affiliates to continue, to perform each of their obligations as the "local agent" in mainland China and to take such actions in accordance with the provisions of this Agreement and the Ancillary Agreements.

(c) **Taiwan.** As of the Effective Date, CANbridge's Affiliate is the registered Marketing Authorization holder of the Licensed Product as granted by the Taiwan Food and Drug Administration of Taiwan that references PUMA's Marketing Authorization approved by the FDA. Notwithstanding Section 4.4(a), to facilitate the distribution of the Licensed Product in Taiwan, PUMA agrees to permit CANbridge to continue to reference PUMA's Marketing Authorization approved by the FDA after the Effective Date, provided, upon written notice by PUMA or a Designee specified in writing by PUMA to CANbridge, PUMA and CANbridge shall, in coordination with a Designee specified in writing by PUMA, promptly terminate, cancel or otherwise deregister such Marketing Authorization from Taiwan and register a new Marketing Authorization in Taiwan that references PFM's Marketing Approval as approved by the EMA ("**Taiwan MA Registration**"). From the Effective Date until the effective date of the applicable Taiwan MA Registration, pursuant this Section 4.4(c), CANbridge shall, and shall cause its Affiliates to continue, to perform each of their obligations

as the Marketing Authorization holder of the Licensed Products in Taiwan and to take such actions in accordance with the provisions of this Agreement and the Ancillary Agreements.

(d) **Hong Kong**. As of the Effective Date, CANbridge is the registered Marketing Authorization holder of the Licensed Product as granted by the Pharmacy and Poisons Board of Hong Kong that references PUMA's Marketing Authorization approved by the FDA. Notwithstanding Section 4.4(a), to facilitate the distribution of the Licensed Product in Hong Kong, PUMA agrees to permit CANbridge to continue to reference PUMA's Marketing Authorization approved by the FDA after the Effective Date, provided, upon written notice by PUMA or a Designee specified in writing by PUMA to CANbridge, PUMA and CANbridge shall, in coordination with a Designee specified in writing by PUMA, promptly terminate, cancel or otherwise deregister such Marketing Authorization from Hong Kong and register a Marketing Authorization in Hong Kong that references PFM's Marketing Approval as approved by the EMA ("**HK MA Registration**"). From the Effective Date until the effective date of the applicable HK MA Registration, pursuant this Section 4.4(d), CANbridge shall, and shall cause its Affiliates to continue, to perform each of their obligations as the entity of record on the certificate of sale for the Licensed Products in Hong Kong and to take such actions in accordance with the provisions of this Agreement and the Ancillary Agreements.

(e) **Obligations.**

(i) PUMA and a Designee specified in writing by PUMA shall receive all advanced drafts of documents to be filed with a Governmental Authority pursuant to this Section 4.4 and shall be provided with reasonable amount of time to review and comment on the same prior to filing. CANbridge shall, and shall cause its Affiliate to, consider in good faith any reasonable comments timely provided by PUMA or such Designee.

(ii) In accordance with the TSA, [***], in each case, pursuant to the terms of this Agreement and the TSA, unless otherwise agreed by the Parties or between CANbridge and such Designee in the Ancillary Agreements.

(iii) CANbridge shall, and shall cause its Affiliates to maintain, each Marketing Authorizations, all local agent statuses and certificates of sale, and related Regulatory Filings held by CANbridge or its Affiliates in force and good standing until the relevant transfer or termination is effective pursuant to the terms of this Agreement and/or the Ancillary Agreements.

(iv) Unless otherwise required by applicable Law and as may be agreed between the Parties, CANbridge shall use Commercially Reasonable Efforts to continue with any pending Regulatory Filings filed by CANbridge or its Affiliates prior to the Effective Date that relate to the Licensed Products in the Territory.

4.5 **Communications with Governmental Authorities.**

(a) CANbridge shall, and shall cause its Affiliates to, inform PUMA and a Designee specified in writing by PUMA, if CANbridge or its Affiliates receive any communication from any Governmental Authorities with respect to the Licensed Products in the Territory, including with respect to market access, within [***] Business Days after it receives such communication. CANbridge shall, and shall cause its Affiliates to, provide to PUMA and such Designee, any information and documents in relation thereto and shall take into account PUMA's and such Designee's reasonable input with respect to any action or communication to be taken in response to such concern or communication.

(b) If CANbridge or its Affiliates initiate, respond to, file, submit or otherwise communicate with a Governmental Authority in the Territory in connection with the Licensed Products, such

entity shall promptly notify PUMA and a Designee specified in writing by PUMA prior to making any such filing, submission or communication to a Governmental Authority and provide PUMA and such Designee with (i) a copy of the proposed filing, submission or communication and (ii) expected date filing, submission or communication. CANbridge shall, and shall cause its Affiliates to, consider PUMA's and such Designee's comments in good faith.

(c) If CANbridge or its Affiliates receive any communications from a Governmental Authority in the Territory in connection with the Licensed Products, such entity shall promptly notify PUMA and a Designee specified in writing by PUMA. Notwithstanding the foregoing, CANbridge shall, and shall cause its Affiliates to (i) provide PUMA and a Designee specified in writing by PUMA with written updates as to the transfer of the Regulatory Filings, Marketing Authorization and change of "local agents" in the applicable Region in the Territory, on an ongoing basis, (ii) promptly notify PUMA and such Designee of any material communication (whether written or oral) from a Governmental Authority in relation to such transfer or change, (iii) provide PUMA and such Designee reasonable notice of all meetings and telephone calls with any Governmental Authority that may have a material impact upon such transfer or change, (iv) provide PUMA and such Designee a reasonable opportunity to participate at each such meeting or telephone call; and (v) notify PUMA and such Designee in writing of the effectiveness of such transfer or change and the anticipated effective dates, promptly following the applicable Governmental Authority's approval of such transfer or change.

4.6 **Further Assurances**.

(a) From time to time after the Effective Date, CANbridge shall, and shall cause its Affiliates to, execute and deliver to PUMA or a Designee specified in writing by PUMA, all such instruments and documents PUMA or a Designee may reasonably request in order to effect the intent of this Agreement.

(b) CANbridge shall, and shall cause its Affiliates to perform certain activities related to quality and pharmacovigilance with respect to the Licensed Products in the Territory, as provided in the TSA.

(c) Upon completion of the applicable activities contemplated under Sections 4.4 and 4.5, except as required by applicable Law or otherwise agreed by the Parties or pursuant to any Ancillary Agreement, CANbridge's rights, responsibilities and obligations with respect to the Regulatory Filings and Marketing Authorizations in connection with the Licensed Products in the Territory shall terminate.

4.7 **Licenses Upon Termination**. CANbridge hereby grants to PUMA:

(a) a non-exclusive, fully paid-up, royalty-free, worldwide, transferable, perpetual and irrevocable license, with the right to sublicense, under any intellectual property rights Controlled by CANbridge claiming Inventions that are necessary or reasonably useful to make, use, sell, offer for sale, or import the Licensed Products as they exist as of the Effective Date (if any) ("**Product Inventions and IP**") to make, use, sell, offer for sale, or import the Licensed Products; and

(b) Within [***] days from the Effective Date, CANbridge shall assign to PUMA all trademarks and logos owned by CANbridge or its Affiliates identifying the Licensed Products, excluding for clarity all Trademarks also used in connection with CANbridge's business other than with respect to the Licensed Products (the Trademarks to be assigned, the "**Product Trademarks**"). The Product Trademarks include without limitation those Trademarks listed in Schedule 4.7(b) (Product Trademarks).

(c) CANbridge shall [***], and PUMA shall [***], provided, however [***]. CANbridge shall not [***]. As from the Effective Date, CANbridge shall not use and shall cause any of its Affiliates not to use any of the Product Trademarks, except as otherwise provided herein or in the Ancillary Agreements.

4.8 **Return of Confidential Information**. Within [***] days of the Effective Date, each Party will, and cause its Affiliates to (a) destroy, all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or Control, and provide written certification of such destruction, or (b) prepare such tangible items of the other Party's Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, notwithstanding the foregoing, in any event, (i) each Party may retain the Confidential Information of the other Party to the extent necessary to perform its obligations under this Agreement and the Ancillary Agreements; and (ii) such first Party may retain one (1) copy of such Confidential Information of the other Party for its legal archives; provided, further, however, and notwithstanding the foregoing to the contrary, PUMA and its Designee may also retain one (1) copy of the Confidential Information of CANbridge to the extent such Confidential Information is necessary or reasonably useful to make, use, sell, offer for sale, or import the Licensed Products to make, use, sell, offer for sale, or import the Licensed Products and to otherwise exercise its rights granted under this Agreement.

4.9 **Third-Party Agreements; Transfer of Know-How**. Within [***] days following the Effective Date, as requested by PUMA or a Designee, and unless otherwise provided in the Ancillary Agreements, CANbridge shall, and shall cause its Affiliates to, assign all of its right, title and interest in and to any Third Party agreements that solely relate to the Licensed Product and not to another product ("**Third Party Agreement**") to PUMA or a Designee specified in writing by PUMA unless, with respect to any such Third Party Agreement, such Third Party Agreements do not permit such assignment, in which case CANbridge shall use Commercially Reasonable Efforts, and cause its Affiliates to use Commercially Reasonable Efforts, to waive any exclusive dealing obligations of such Third Party with respect to such Third Party Agreement, and to provide to PUMA information relevant to the Third Party Agreement and make introductions to such Third Party so that PUMA or such Designee may enter into direct discussions with such Third Party to secure the relevant items or services; provided that, for clarity, the foregoing obligation shall not require CANbridge to negotiate with such Third Party on PUMA's or such Designee's behalf. Promptly following the Effective Date, at PUMA's or its Designee's request, CANbridge shall, and shall cause its Affiliates to, provide copies to PUMA or a Designee specified in writing by PUMA of any Know-How in CANbridge's possession or control that (a) is reasonably useful or necessary to make, use, sell, offer for sale, or import the Licensed Products and (b) developed by CANbridge, its Affiliates, Sublicensees; contractors or vendors under the Terminated Agreements and Documents in the course of performing its obligations and exercising its rights under this Agreement. Such Know-How shall include without limitation customer lists, but only to the extent such customer lists relate solely to the Licensed Product and not another product.

4.10 **PUMA's Representations and Warranties**. PUMA represents and warrants to CANbridge as follows as of the Effective Date:

(a) **Entity Status**. PUMA is a legal entity duly organized, validly existing and, where applicable, in good standing under the Laws of its jurisdiction of its organization or incorporation.

(b) **Authority**. PUMA has the requisite corporate power and authority to enter into this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated to be consummated by it hereby. The execution and delivery of this Agreement and the consummation of the transactions contemplated to be consummated by it hereby have been duly authorized by all necessary corporate actions of PUMA. This Agreement (assuming the due authorization, execution and delivery hereof by CANbridge) constitutes, the valid and legally binding obligation of PUMA, enforceable against PUMA in accordance with its terms,

subject to (i) applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally and (ii) the remedy of specific performance and injunctive and other forms of equitable relief.

(c) **Non-Contravention**. The execution, delivery and performance by PUMA of this Agreement and the consummation of the transactions contemplated hereby and the execution, delivery and performance by PUMA, do not and will not violate the articles of incorporation or bylaws or comparable organizational documents of PUMA, as applicable.

(d) **Litigation**. Except for the matters described in this Agreement, to PUMA's knowledge, there is no litigation, claim, investigation, or administrative action of any Governmental Authority, pending or threatened against PUMA or any of its Affiliates before any Governmental Authority in the Territory.

4.11 **CANbridge's Representations and Warranties**. CANbridge represents and warrants to PUMA as follows as of the Effective Date:

(a) **Entity Status**. CANbridge is a legal entity duly organized, validly existing and, where applicable, in good standing under the Laws of its jurisdiction of its organization or incorporation.

(b) **Authority**. CANbridge has the requisite corporate power and authority to enter into this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated to be consummated by it hereby. The execution and delivery of this Agreement and the consummation of the transactions contemplated to be consummated by it hereby have been duly authorized by all necessary corporate actions of CANbridge. This Agreement (assuming the due authorization, execution and delivery hereof by PUMA) constitutes, the valid and legally binding obligation of CANbridge, enforceable against CANbridge in accordance with its terms, subject to (i) applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally and (ii) the remedy of specific performance and injunctive and other forms of equitable relief.

(c) **Non-Contravention**. The execution, delivery and performance by CANbridge of this Agreement and the consummation of the transactions contemplated hereby and the execution, delivery and performance by CANbridge, do not and will not (i) violate the articles of incorporation or bylaws or comparable organizational documents of CANbridge, as applicable, (ii) materially violate any Law or other restriction of any Governmental Authority in the Territory applicable to CANbridge, the Exploitation of the Licensed Products in the Field and the Territory or violate any judgment of a Governmental Authority to which CANbridge is subject in respect of the Exploitation of the Licensed Products in the Field and the Territory, (iii) materially violate, breach or constitute a default under (with or without notice, lapse of time, or both) or give rise to or result in the termination, cancellation, acceleration of any obligation, or the loss of any benefit under any Regulatory Filings or Marketing Authorizations related to the Licensed Products, or (iv) result in the creation of any encumbrance in the Exploitation of the Licensed Products.

(d) **Entirety; No Litigation; Consents**.

(i) Neither CANbridge nor any of its Affiliates have granted any licenses or sublicenses to any Person under any Licensed Patents, Licensed Know-How and/or Licensed Trademarks.

(ii) Neither CANbridge nor any of its Affiliates have received written notice that any Person has asserted a claim of ownership or right of possession or use in or to any of the assets to be transferred to PUMA or a Designee pursuant to the terms of this

Agreement. All of the inventory, stock, marketing materials, Regulatory Filings, Marketing Authorizations and any other assets and rights that are owned or controlled by CANbridge and transferred or licensed to PUMA or a Designee specified by writing by PUMA pursuant to this Agreement are free and clear of all encumbrances and constitute all of CANbridge's assets or rights related the Exploitation of the Licensed Products as they exist as of the Effective Date except as set forth in the Ancillary Agreements.

(iii) Except for the matters described in this Agreement, there is (x) no litigation, claim, investigation, or administrative action of any Governmental Authority, pending or, to CANbridge's knowledge, threatened against CANbridge or any of its Affiliates before any Governmental Authority in the Territory (A) in respect of the Exploitation of the Licensed Product in the Field and the Territory or (B) that, if successful, could reasonably be expected to result in restraining, enjoining, or otherwise preventing the completion by CANbridge or its Affiliates of the transactions contemplated by this Agreement and (y) no judgment in the Territory to which CANbridge or any of its Affiliates is subject in respect of the Exploitation of the Licensed Product in the Field and the Territory.

(iv) Except for the filings, registrations, notifications, permits or authorizations as set forth in this Agreement, no notice to, filing with, permit of, authorization of, exemption by, or consent of, any Governmental Authority is required for CANbridge or its Affiliates to consummate the transactions contemplated hereby and/or by the Ancillary Agreements.

(e) **Compliance with Law**. CANbridge and its Affiliates and, to CANbridge's knowledge, contractors or vendors under the Terminated Agreements and Documents, with respect to the Exploitation of the Licensed Products, are in compliance with all applicable Laws in the Territory. CANbridge and its Affiliates and, to CANbridge's knowledge, Sublicensees, contractors or vendors under the Terminated Agreements and Documents have not received any written notices alleging any such noncompliance with applicable Law with respect to the Exploitation of the Licensed Product.

(f) **Anti-Corruption**. Neither CANbridge, nor any Affiliate of CANbridge or. to CANbridge's knowledge, contractors or vendors under the Terminated Agreements and Documents or any representative acting on behalf of CANbridge or any Affiliate of CANbridge, in each case, in connection with the Exploitation of the Licensed Product in the Territory, has, in violation of any Anti-Corruption Laws, offered, given, promised or authorized the giving of anything of value, directly or indirectly, to any Person, including any Public Official or Entity, including for the purpose of influencing any action or decision of a Public Official or Entity in his or her official capacity to assist CANbridge in obtaining or retaining business or any business advantage, or directing business to, any Person.

(g) **Regulatory Matters**.

(i) CANbridge or its Affiliate is the "local agent" listed in connection with the Marketing Authorization of the Licensed Product issued by NMPA in mainland China and CANbridge or its respective Affiliate is the Marketing Authorization holder of the Licensed Product in Taiwan and Hong Kong issued by the Taiwan Food and Drug Administration of Taiwan and the Pharmacy and Poisons Board of Hong Kong, respectively, in each case, that references PUMA's Marketing Authorization approved by the FDA.

(ii) Each Marketing Authorization, including each certificate or local agent status, issued or granted by the applicable Regulatory Authorities is in full force and effect.

(iii) CANbridge is the holder of all filings for Pricing and Reimbursement Approval in connection with the Licensed Products in the Territory as of the Effective Date.

(iv) No litigation is pending or threatened regarding the revocation, cancellation, rescission, suspension, withdrawal, modification, or refusal to renew in the ordinary course any Marketing Authorization of the Licensed Products in the Territory, nor has any event occurred, to CANbridge's knowledge, that would reasonably be expected to give rise to any right of notice, modification, acceleration, payment, cancellation, withdrawal, limitation, or termination of a Marketing Authorization issued by the Regulatory Authorities of mainland China, Hong Kong and Taiwan, respectively.

(v) Neither CANbridge, any of its Affiliate, nor to CANbridge's knowledge, any of its contractors or vendors under the Terminated Agreements and Documents have received any written communication from any Governmental Authority threatening to revoke, cancel, rescind, suspend, withdraw, modify, or refuse to renew any Marketing Authorization issued by the Regulatory Authorities of mainland China, Hong Kong and Taiwan, respectively, that has not been withdrawn or otherwise remedied.

(vi) Neither CANbridge, any of its Affiliates, nor to CANbridge's knowledge, any of its Sublicensees, contractors or vendors under the Terminated Agreements and Documents are in violation of the terms of any Marketing Authorization, including certificate of sale, of the Licensed Products issued by the Regulatory Authorities of mainland China, Hong Kong and Taiwan, respectively, or its rights as "local agent" in mainland China, Hong Kong and Taiwan, respectively.

(vii) Neither CANbridge, any of its Affiliates, nor to CANbridge's knowledge, any of its contractors or vendors under the Terminated Agreements and Documents have initiated an application for a Marketing Authorization, including a certificate of sale, with respect to the Licensed Products in Macao and neither is aware of any information that would hinder the application for or the grant of such Marketing Authorization, including a certificate of sale.

(viii) All fees and charges with respect to each Licensed Product Marketing Authorization, including a certificate of sale, as issued by the Regulatory Authorities of mainland China, Hong Kong and Taiwan, respectively, that have become due and payable have been paid in full, and all required applications, notices, and required filings (including any pending renewal applications, notices, or filings) with respect to such Marketing Authorizations, including a certificate of sale, have been duly filed or made on a timely basis with the appropriate Governmental Authorities.

(ix) Neither CANbridge, any of its Affiliates nor, to CANbridge's knowledge, any Sublicensees or Third Party contractors under the Terminated Agreements and Documents have been subject to physical inspections or received inspection reports from any applicable Governmental Authority in the Territory, in which such Governmental Authority has asserted or alleged that the operations of CANbridge, any of its Affiliates, Sublicensees or any Third Party contractors were or are not in compliance with any applicable Laws.

(x) There has not been any claim for injury or property damage as a result of any defect or other deficiency (whether of design or materials) with respect to any Licensed Product used or sold by or on behalf of CANbridge in the Territory, and to CANbridge's knowledge, there is no fact or circumstance that may lead to such claim.

(h) **Intellectual Property**.

(i) CANbridge is the sole owner of, or otherwise has the exclusive right to own, or direct transfer of ownership of, the Product Trademarks.

(ii) Schedule 4.11(h) (Registered Product TMs), sets forth a true and complete list of all Product Trademarks that have been issued by or registered with a Governmental Authority in the Territory, or that is the subject of an application for registration or issuance by a Governmental Authority in the Territory, in each case, that has not been abandoned or withdrawn ("**Registered Product TMs**"). For each listed item, Schedule 4.11(h) sets forth, as applicable, the owner of such Registered Product TM, registration or application number, the filing and expiration dates thereof. All required maintenance fees, annuity fees or renewal fees for each Registered Product TM that are due and payable prior to the Effective Date have been paid prior to the Effective Date. To CANbridge's knowledge, no Registered Product TM has been adjudged by a Governmental Authority to be invalid or unenforceable, in whole or in part, and all Registered Product TMs, that are registered or has been granted or issued, are valid and enforceable. No Product Trademarks that are or were Registered Product TMs have been unintentionally permitted to lapse or enter the public domain.

(iii) Except for Product Trademarks owned by PUMA, Product Trademarks are wholly and exclusively owned by CANbridge or CANbridge has the right to own or direct transfer of ownership of (free and clear of all encumbrances) or license, the Product Trademarks.

(iv) CANbridge has not granted any licenses or sublicenses to any Third Party in or with respect to any of the Product Trademarks other than grants of rights to distribute the Licensed Products, and grants of rights to advertising and marketing firms, vendors and other subcontractors in the ordinary course of business.

(v) To CANbridge's knowledge, the Exploitation of the Licensed Products in the Field in the Territory does not and will not infringe or misappropriate any Third Party's Intellectual Property Rights or constitute unfair competition or trade practices under the Laws of any jurisdiction in the applicable Territory in which the Licensed Products are commercially available. No litigation is pending or, to CANbridge's knowledge, threatened against CANbridge or any of its Affiliates (i) based upon, challenging, seeking to deny or restrict the use and the validity of any of the Product Inventions and IP and Product Trademarks or (ii) alleging that CANbridge, any of its Affiliates' Exploitation of the Licensed Products or that CANbridge's, or any of its Affiliates' Exploitation of the Licensed Products infringes or misappropriates any Third Party's Intellectual Property Rights or constitutes unfair competition or trade practices under the Laws of any jurisdiction in the Territory, and to CANbridge's knowledge, there are no facts or circumstances that could lead to such a claim. CANbridge and its Affiliates have not received any a written allegation by such Third Party that the Exploitation of the Licensed Product by CANbridge or any of its Affiliates in the Territory has infringed or misappropriated any of the Intellectual Property of such Person. There is, and has been no pending, decided or settled opposition, interference, reexamination, cancellation, litigation, or judgment related to the Product Trademarks, and to CANbridge's knowledge, there are no fact or circumstances that could lead to such a claim. Product Trademarks (together with the rights and services provided or granted to a Designee under this Agreement) include all of the Intellectual Property used by CANbridge or any of its Affiliate to conduct the Exploitation of the Licensed Product prior to the Effective Date.

(vi) To CANbridge's knowledge, no Third Party is engaging in any activity that infringes or misappropriates the Product Trademarks in the Territory.

(vii) CANbridge has taken commercially reasonable measures consistent with industry practice in the pharmaceutical industry to maintain the confidentiality and value of all of PUMA's Confidential Information that is used or held for use in connection with the Exploitation of the Licensed Products. To CANbridge's knowledge, no trade secrets with respect to the Licensed Product have been disclosed by CANbridge or any of its Affiliates to any Person, except pursuant to valid non-disclosure or license agreements. CANbridge has taken commercially reasonable measures consistent with industry practice in the pharmaceutical industry to ensure that any employee or contractor who has conceived, developed or created any of the Product Inventions and IP for CANbridge, any of its Affiliates or Sublicensees, contractors or vendors is the subject of a valid and legally enforceable contract or other valid and legally enforceable arrangement with such Person with respect thereto transferring to CANbridge such Person's right, title and interest therein and thereto. To CANbridge's knowledge, no employee or contractor who has conceived, developed or created any Product Inventions and IP owns any right, title, or interest in or to the Product Inventions and IP conceived, created or developed by such Person during his or her employment or other engagement with CANbridge, any of its Affiliates or Sublicensees, contractors or vendors and no such employee or contractor has asserted any such claim to CANbridge, any of its Affiliates or Sublicensees, contractors or vendors.

(viii) As of the Effective Date, CANbridge or its Affiliates have not filed or registered any claims in any Patent Rights that cover or claim any Product Inventions and IP.

(ix) As of the Effective Date, there are no fees, annuity fees or renewal fees that have accrued, or are otherwise payable in connection with the prosecution, registration or maintenance in connection with any CANbridge Product Patents.

(i) **Relationships with Third Parties**. No contractor that is party to a Third Party Agreement has canceled or otherwise terminated, or provided written notice to CANbridge or any of its Affiliates of its intent, or threatened in writing to terminate its relationship with CANbridge with respect to such Third Party Agreement.

(j) **Data Protection**. CANbridge and its Affiliates are, and to CANbridge's knowledge its Sublicensees, contractors or vendors are, and have for the past [***] years prior to the Effective Date been, in material compliance with all Laws relating to the collection, use, disclosure, retention, protection or processing of Personal Data (collectively, the "**Data Protection Requirements**") in connection with the Exploitation of the Licensed Product. In the past [***] years prior to the Effective Date, with respect to the Licensed Product: (x) CANbridge and its Affiliates have not, and to CANbridge's knowledge its Sublicensees, contractors or vendors have not, received any written notice from any data protection Governmental Authority alleging non-compliance with any Data Protection Requirement; (y) CANbridge and its Affiliates have not, and to CANbridge's knowledge its Sublicensees, contractors or vendors have not, received any written notice from any data subject alleging any non-compliance with any Data Protection Requirement; and (z) to CANbridge's knowledge, the processing of Personal Data by CANbridge or its Affiliates or its Sublicensees, contractors or vendors have not, been the subject of any investigation or proceedings (whether of a criminal, civil or administrative nature) by any Governmental Authority. CANbridge and its Affiliates have taken, and to CANbridge's knowledge its contractors and vendors have taken, commercially reasonable measures consistent with industry practice in the pharmaceutical industry and have implemented appropriate administrative, technical, physical

and contractual measures to comply in all material respects with Data Protection Requirements, including in its arrangements with Third Party service providers that process Personal Data on its behalf. Each of CANbridge, its Affiliates, and to CANbridge's knowledge each of its contractors and vendors, has implemented and maintains appropriate policies and procedures designed to protect Personal Data and its trade secrets. In the past [***] years prior to the Effective Date, to CANbridge's knowledge, CANbridge, its Affiliates and contractors have not experienced any actual, suspected or alleged security incident in which an unauthorized party accessed any Personal Data or acquired Personal Data or trade secrets maintained by or on behalf of CANbridge, its Affiliates or contractors.

(k) **Ancillary Agreements**. Other than the Ancillary Agreements, there are no other agreements, contracts, letters or understandings, whether written or oral, between CANbridge or its Affiliates and any Designee.

4.12 **Covenants.** CANbridge covenants as follows:

(a) **Cooperation in Litigation and Investigations**. CANbridge shall reasonably cooperate with PUMA or a Designee specified in writing by PUMA in the defense or prosecution of any litigation, examination or audit instituted by a Third Party prior to the Effective Date or that may be instituted by a Third Party thereafter against or by either Party, a Designee or any of their respective Affiliates relating to or arising out of the Exploitation of the Licensed Product by or on behalf of CANbridge prior to or after the Effective Date for a period of [***] years from the Effective Date. Subject to Section 4.12(c) below, CANbridge shall, and shall cause its Affiliates to, make available to PUMA or a Designee specified in writing by PUMA all records to the extent relating to the Licensed Products held by CANbridge or its Affiliates under the Terminated Agreements and Documents and reasonably necessary to permit the defense or investigation of any such litigation, examination or audit; provided, however, that the production of such Documents is not contrary to Law or court order. For clarity, the foregoing obligations under this Section 4.12(a) excludes requests made in connection with any litigation by and among the Parties, a Designee or any of their respective Affiliates arising out of this Agreement or any of the Ancillary Agreements.

(b) **Retention of Records.** CANbridge shall, and shall cause its Affiliates to, preserve and retain all records referred to in Section 4.2 for the length of time contemplated by CANbridge's standard record retention policies and schedules. After the Effective Date, CANbridge shall, and shall cause its Affiliates to, grant to PUMA or a Designee specified by writing by PUMA such access to financial records and other information in its possession related to the Exploitation of the Licensed Products and to provide such other cooperation and assistance, in each case, as shall be reasonably required to enable PUMA or such Designee to complete their legal, regulatory, stock exchange and financial reporting requirements and for any other reasonable business purpose, including in respect of litigation and insurance matters. PUMA or such Designee shall promptly [***]. For clarity, the foregoing obligations under this Section 4.12(b) exclude requests made in connection with any litigation by and among the Parties, a Designee or any of their respective Affiliates arising out of this Agreement or any of the Ancillary Agreements.

(c) **Exception.** Notwithstanding the obligations in this Section 4.12, CANbridge shall not be required to make available such documents if such disclosure could, in CANbridge's reasonable judgment, (i) violate applicable Law or any binding agreement entered into prior to the Effective Date (including any confidentiality agreement to which CANbridge or any of its Affiliates is a party), (ii) jeopardize any attorney-client privilege or other established legal privilege, protection, or immunity, or (iii) disclose any trade secrets (provided, that CANbridge shall use, and shall cause its Affiliates to use, Commercially Reasonable Efforts to make such disclosure in a manner that does not result in the occurrence of any of the items

described in the preceding clauses (i) through (iii), and, in any case, CANbridge shall identify to PUMA or a Designee specified in writing by PUMA any such withheld information at such time, such as the entry into a joint defense agreement or other arrangement to avoid loss of attorney-client privilege). If PUMA or a Designee specified in writing by PUMA requests any cooperation or books and records under this Section 4.12, such requesting party shall [***].

(d) **Non-Competition.**

(i) To the extent permitted by Laws, to protect PUMA's and each Designee's interest in the Exploitation of the Licensed Product in the Field and the Territory and in consideration of the benefits CANbridge will receive pursuant to the terms of this Agreement, CANbridge shall not, and shall cause its Affiliates to not, directly or indirectly through any Third Party (a) [***], or (b) [***].

(ii) Notwithstanding Section 4.12(d)(i), in the event that CANbridge is acquired by a Third Party and such Third Party [***], the further Exploitation of such [***] by such Third Party and its Affiliates after the consummation of the applicable acquisition transaction will not constitute a violation of this Section 4.12(d) so long as such Third Party and its Affiliates do not use or have access to any Confidential Information of PUMA or any of the Designees (whether relating to the clinical development or commercialization of any Licensed Products or otherwise).

(iii) [***].

(e) **Non-Disparagement.** Each Party agrees not to, and shall use commercially reasonable efforts to ensure that its representatives, agents, attorneys, and any other persons or entities that such Party controls do not, make any public statements, including statements to any news or other media outlets, current or prospective customers, current or prospective investors, competitors, or industry groups or analysts, either written or verbal, or cause or encourage others to make any public statements, written or verbal, that criticize, defame or disparage the personal or business reputation, practices, products or conduct of any other Party or a Designee. The Parties agree that any breach of the Confidentiality provision or the Non-Disparagement provision of this Agreement may entitle the non-breaching party to both monetary damages and injunctive relief.

5. DIRECT INDEMNIFICATION.

5.1 **Indemnification by [***]**. [***] shall indemnify, defend and hold harmless [***] Indemnified Parties from and against all damages, losses and liabilities (including reasonable attorney's fees and expenses) ("[***] **Indemnified Parties Losses**") arising from (a) [***], (b) [***] or (c) [***].

5.2 **Indemnification Claim Procedure for Direct Claims**.

(a) In the event of a claim made by a [***] Indemnified Party (the "**Indemnified Party**") for any claims arising under Section 5.1, the Indemnified Party shall give reasonably prompt written notice to [***] (the "**Indemnifying Party**"), which notice (an "**Indemnification Notice**") shall: (i) state that the Indemnified Party has paid or properly accrued or reasonably anticipates that it will have to pay or accrue [***] Indemnified Parties Losses that are subject to indemnification pursuant to Section 5.1, (ii) specify in reasonable detail (to the extent known by the Indemnified Party) the individual items and amounts of such [***] Indemnified Parties Losses, the date each such item was paid or properly accrued, or the basis for such anticipated liability, and a description of the basis of such Indemnified Party's claim for indemnification and (iii) to the extent practicable, include any other material details pertaining thereto, along with copies of the relevant documents evidencing such claim and the basis for indemnification

sought (to the extent within its possession and disclosure is not proscribed by Law or contract and would not jeopardize any attorney-client privilege or other established legal privilege); *provided, however*, that no delay or failure on the part of the Indemnified Party in delivering an Indemnification Notice shall relieve the Indemnifying Party of its indemnification obligations under this Agreement except to the extent that the Indemnifying Party is actually and materially prejudiced by such delay or failure.

(b) If an Indemnifying Party objects in writing to any claim or claims made in any Indemnification Notice, the Indemnifying Party and the Indemnified Party shall attempt in good faith for a period of [***] days following the Indemnified Party's receipt of such objection notice to agree upon the respective rights of such parties with respect to each of such claims. If agreement on all of such disputed claims is not reached after such [***]-day period of good faith negotiation, either the Indemnifying Party or the Indemnified Party may initiate the dispute resolution proceedings provided in Article 13 of the License Agreement.

(c) **Payment.** In the event that the Indemnifying Party agrees to or is determined pursuant to any enforceable order pursuant to Section 5.1(a) to have an obligation to reimburse the Indemnified Party for the [***] Indemnified Parties Losses, the Indemnifying Party shall, subject to the provisions of this Article 5, promptly (but, in any event, within [***] days) following such agreement or determination (including as set forth in this Section 5.2(c)) pay such amount to the Indemnified Party by wire transfer of immediately available funds to the account specified in writing by the Indemnified Party

5.3 **Liability Limitations Solely with Respect to [***] Indemnified Parties Losses**.

(a) Notwithstanding anything in this Agreement to the contrary, in no event shall [***] have liability under this Agreement to a [***] Indemnified Party for any [***] Indemnified Parties Losses or other damages, losses or liabilities that result from a breach of one or more [***], unless the aggregate amount of all such [***] Indemnified Parties Losses exceeds [***], in which event [***] shall be required to pay the amount of such [***] Indemnified Parties Losses from the first dollar, up to a maximum amount equal to [***].

(b) Notwithstanding anything in this Agreement to the contrary, [***]'s liability under this Agreement in connection with any [***] Indemnified Parties Losses or other damages, losses or liabilities incurred by a [***] Indemnified Party shall not exceed, in the aggregate, [***], except in the case of gross negligence, willful misconduct or fraud by [***] or its Affiliates.

(c) Except as expressly permitted under this Agreement, neither Party shall have any right of setoff of any amounts due and payable, or any Liabilities arising, under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under any Ancillary Agreement. The payment obligations under each of this Agreement and the Ancillary Agreements remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the respective Ancillary Agreements.

(d) Notwithstanding anything to the contrary under this Agreement or any Ancillary Agreement, (i) [***] shall not be required to indemnify or otherwise provide recourse to [***] Indemnified Parties more than once for the same damages, losses or liabilities pursuant to this Agreement, any Ancillary Agreement or otherwise and (ii) no [***] Indemnified Party may obtain indemnity or other recourse for the same damages, losses or liabilities more than once under this Agreement or any Ancillary Agreement or otherwise.

6. NON-EXCLUSIVE REMEDY.

6.1 Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at Law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this Agreement, provided, however, solely with respect to the [***] Indemnified Parties Losses, subject to Article 11 of the License Agreement, the indemnification obligations of the Parties set forth in Article 5 provide the sole and exclusive monetary remedy of the Parties for the breach of the terms of this Agreement as provided under Section 5.1. Notwithstanding the foregoing, nothing in this Agreement shall limit either Party's or any Affiliate of either Party's ability to seek injunctive relief (including specific performance) under this Agreement.

7. CONFIDENTIALITY.

7.1 This Agreement and the terms herein shall the Confidential Information of both Parties. Each Party agrees to, and will cause its Affiliates, sublicensees and contractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party.

7.2 **Permitted Disclosures**. Each Party agrees that it and its Affiliates will provide or permit access to the other Party's Confidential Information only to the receiving Party's employees, consultants, advisors and sublicensees, and to the employees, consultants and advisors of the receiving Party's Affiliates, in each case on a need to know basis who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 7.2 (Confidential Information); provided, however, that each Party will remain responsible for any failure by its Affiliates and sublicensees, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under this Section 7.2 (Confidential Information) as if such Affiliates, employees, consultants, advisors and sublicensees were parties directly bound to the requirements of this Section 7.2 (Confidential Information).

7.3 **Confidentiality Limitation**. Notwithstanding anything to the contrary herein, each Party may use and disclose the other Party's Confidential Information as follows: (a) under appropriate written confidentiality obligations substantially equivalent to those in this Agreement, to its Affiliates, potential and actual permitted sublicensees, contractors and any other Third Parties, to the extent such use or disclosure is reasonably necessary to perform its obligations or to exercise its rights under this Agreement, (b) to its advisors (including financial advisors, attorneys and accountants), actual or potential acquisition partners, financing sources or investors and underwriters on a need to know basis, in each case under appropriate confidentiality obligations (which may include professional ethical obligations) substantially equivalent to those in this Agreement; provided, however, that each Party will remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under Section 7.2 (Confidential Information) as if such individuals were parties directly bound to the requirements of this Section 7, or (c) as required by any court or other governmental body or as otherwise required by applicable Law (including any such disclosures as are required by a Regulatory Authority in connection with seeking Regulatory Approval for any Licensed Product in the Territory); provided, that, notice is promptly given to the other Party and the disclosing Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information.

8. [RESERVED.]

9. ACCRUED OBLIGATIONS; SURVIVING OBLIGATIONS.

(a) Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, on the effective date of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

(b) Notwithstanding anything to the contrary in this Agreement:

(i) The representations and warranties of CANbridge set forth in Sections 4.11(a) (Entity Status), 4.11(b) (Authority), 4.11(c) (Non-Contravention), 4.11(d) (Entirety; No Litigation; Consents), 4.11(e) (Compliance with Law), 4.11(f) (Anti-Corruption), 4.11(g) (Regulatory Matters) and 4.11(h) (Intellectual Property) shall survive for [***] following the Effective Date. The representations and warranties of CANbridge set forth elsewhere in this Agreement [***] will survive for [***] after the Effective Date.

(ii) The representations and warranties of PUMA will survive for [***] years following the Effective Date.

(iii) The covenants and agreements contained in this Agreement that contemplate performance by either Party shall survive until the latest of (i) the expiration of the term of the undertaking set forth in this Agreement and (ii) [***] years following the Effective Date.

10. MISCELLANEOUS

10.1 **Assignment; Successors**. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party without the prior written consent of the other Party; provided, however, that PUMA may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent, to an Affiliate or to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization or similar transaction, subject to the assignee agreeing in writing to be bound by the terms and conditions of this Agreement. Any assignment in violation of this Section 10.1 (Assignment) shall be null and void. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party.

10.2 **Choice of Law**. This Agreement, the rights and obligations of the Parties under this Agreement and any claim or controversy directly or indirectly based upon or arising out of this Agreement (whether based on contract, tort, or any other theory), shall be governed by the laws of the State of New York without giving effect to any choice or conflict of law provisions or rule that would cause the application of the laws of any jurisdiction other than the State of New York. Any communication or proceedings resulting of disputes under this Agreement shall be in English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods.

10.3 **Notices**. Any notice or report required or permitted to be given or made under this Agreement by one Party to the other will be in writing and will be deemed to have been delivered (a) upon personal delivery, (b) on the second Business Day (at the place of delivery) next following deposit with a reputable, internationally recognized overnight courier that maintains records of delivery and (c) in the case of notices provided by telecopy (which notice will be followed immediately by an additional

notice pursuant to clause (a) or (b) above if the notice is of a default under this Agreement), upon completion of transmission, with transmission confirmed, to the addressee's facsimile machine, as follows (or at such other addresses or facsimile numbers as may have been furnished in writing by a Party to the other as provided in this Section 10.3 (Notices)). This Section 10.3 (Notices) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to PUMA:	PUMA Biotechnology, Inc. 10880 Wilshire Blvd., Suite 2150 Los Angeles, CA 90024 USA Attention: [***] Fax: [***]
With copies to:	Latham & Watkins 650 Town Center Drive 20th Floor Costa Mesa CA 92626-1925, USA Attention: Charles Ruck Fax: 1-714-755-8290 Latham & Watkins 140 Scott Drive Menlo Park, CA 94025-1008, USA Attention: Judith A. Hasko Fax: 1-650-463-2600
If to CANbridge:	CANbridge Biomed Limited Sterling Centre No. 11 Cheung Yue Street, Kowloon Hong Kong Attention: Chief Executive Officer Fax: [***]
With copies to:	CANbridge Life Sciences Limited 303A Building E Wangjing Pioneer Park No. 2 LizeZhongEr Road Chaoyang District, Beijing, China Attention: Chief Executive Officer Fax: [***] and Ropes & Gray LLP 800 Boylston Street, Prudential Tower Boston, Massachusetts 02199-3600 Attention: David McIntosh, Esq. Fax: 617-235-0507

10.4 **Severability**. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision shall not render any other provision of this Agreement invalid or unenforceable, and all other provisions shall remain in full force and effect and shall be enforceable, unless the provisions that have been found to be invalid or unenforceable shall substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

10.5 **Integration**. This Agreement, and the schedules, exhibits and attachments hereto, constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes the Terminated Agreements and Documents and all other previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

10.6 **Waivers and Amendments**. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein shall not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. No waiver will be effective unless it has been given in writing and signed by the Party giving such waiver, and no provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

10.7 **Independent Contractors; No Agency**. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes.

10.8 **Affiliates, Sublicensees, and Contractors**. To the extent that this Agreement imposes obligations on Affiliates, sublicensees or contractors of a Party, such Party will cause its Affiliates and its sublicensees and contractors to perform such obligations. Either Party may use one or more of its Affiliates, sublicensees or contractors to perform its obligations and duties or exercise its rights under this Agreement; provided, however, that (a) each such Affiliate, sublicensee or contractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement, (b) the performance of any obligations of a Party's by its Affiliates, sublicensees or contractors will not diminish, reduce or eliminate any obligation of such Party under this Agreement, and (c) such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement.

10.9 **Force Majeure**. Neither Party will be responsible to the other for, or be deemed to have defaulted under or breached this Agreement for, any failure or delay in performing any of its obligations under this Agreement or for other nonperformance under this Agreement (excluding, in each case, the obligation to make payments when due) if such delay or nonperformance is caused by or results from events beyond the reasonable control of the non-performing Party, including strike, fire, flood, earthquake, hurricanes, accident, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce

of the non-performing Party or of any other Person), act of terrorism, epidemic, pandemic, act of God or acts, omissions or delays in acting of the government of any country or Region or of any local government, in each case, to the extent unavoidable or beyond the reasonable control of such Party (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement or such Party does not take reasonable mitigation steps) (a "**Force Majeure Event**"). In such event, the Party affected will promptly (and, in any event, within [***] days) notify the other Party in writing of such Force Majeure Event, stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party and will use commercially reasonable efforts to resume performance of its obligations.

10.10 **Third-Party Beneficiaries**. This Agreement is for the sole benefit of the Parties and their Affiliates and their respective successors and permitted assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder. Notwithstanding the foregoing, the Designees shall be express intended third-party beneficiaries of this Agreement and may enforce the provisions hereof as if the Designee was a Party hereto, including by seeking enforce this Agreement directly to the extent that any Designee may deem such enforcement necessary or advisable.

10.11 **Execution in Counterparts; Facsimile Signatures**. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative under seal, in duplicate on the Effective Date.

PUMA Biotechnology, Inc.		**CANbridge BIOMED Limited**	
Signature :	/s/ Alan H. Auerbach	Signature :	/s/ Xue James Qun
Name :	Alan H. Auerbach	Name :	Xue James Qun
Title :	Chief Executive Officer	Title :	Director

In the presence of Pierre Fabre Médicament, SAS

Pierre Fabre Médicament, SAS

Signature : /s/ Jean-Luc Lowinski

Name : Jean-Luc Lowinski

Title : President

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Exhibit 10.3

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

AMENDMENT N°3 TO LICENSE AGREEMENT

This amendment n°3 (this "Amendment") is entered into as of February 24, 2021 (the "Amendment 3 Effective Date"), by and between Puma Biotechnology, Inc., a corporation organized and existing under the laws of the State of Delaware ("Licensor"), and Pierre Fabre Medicament SAS, a corporation organized and existing under the laws of France ("Licensee") (together with Puma, the "Parties" and each individually a "Party"), and amends the License Agreement, dated as of March 29, 2019, as amended, September 17, 2019 and November 21, 2019, respectively (the "Agreement"), by and between Licensor and Licensee. Capitalized terms used but not defined herein have the respective meanings assigned to them in the Agreement.

RECITALS

WHEREAS, Licensor and Licensee are parties to the Agreement pursuant to which Licensor granted to Licensee certain rights and licenses under intellectual property rights owned or controlled by Licensor to Develop and Commercialize the Product (each, as defined in the Agreement) subject to the terms and conditions set forth in the Agreement;

WHEREAS, Licensor and CANbridgepharma Limited, a corporation organized and existing under the laws of Hong Kong, entered into that certain Collaboration and License Agreement, dated as of January 30, 2018 (the "CANbridge License Agreement"), pursuant to which Licensor granted to CANbridgepharma Limited certain rights and licenses to neratinib in mainland China, Hong Kong, Macao and Taiwan;

WHEREAS, CANbridgepharma Limited assigned its interests under the CANbridge License Agreement to its affiliate, CANbridge Biomed Limited, a corporation organized and existing under the laws of Hong Kong ("CANbridge");

WHEREAS, CANbridge and Licensor also entered into other related agreements in connection with the CANbridge License Agreement, including a supply agreement dated August 22, 2019, its corresponding quality and technical agreement dated November 11, 2019, and a safety data exchange agreement dated December 9, 2019 (collectively, and together with the CANbridge License Agreement, the "CANbridge Agreements");

WHEREAS, as of the Amendment 3 Effective Date, Licensor and CANbridge are entering into that certain settlement agreement ("CANbridge Settlement Agreement"), pursuant to which Licensor and CANbridge are settling certain claims and counterclaims described therein related to the CANbridge License Agreement;

WHEREAS, as of the Amendment 3 Effective Date, and pursuant to that certain termination agreement (the "Termination Agreement") between Licensor and CANbridge, Licensor and CANbridge terminated all of the CANbridge Agreements;

WHEREAS, Licensee wants to obtain from Licensor certain rights and licenses under intellectual property rights owned or controlled by Licensor to develop and commercialize neratinib in mainland China, Hong Kong, Macao and Taiwan;

WHEREAS, effective on the Amendment 3 Effective Date, CANbridge and Licensee are entering into certain agreements pursuant to which CANbridge will provide services to Licensee to implement a smooth and efficient transition from CANbridge to Licensee of the ongoing activities with respect to the Product in the China Territory, pursuant to the terms of a transition services agreement ("TSA"), a distribution agreement ("CANbridge Agreement") and the quality agreement and the safety data exchange agreement contemplated therein (collectively, the "Ancillary Agreements"); and

WHEREAS, Licensor and Licensee wish to amend the Agreement through this Amendment to include mainland China, Hong Kong, Macao and Taiwan in the Licensee Territory (as defined in the Agreement), on the terms and conditions set forth in this Amendment.

NOW THEREFORE, the Parties agree as follows:

1. DEFINITIONS

The Parties mutually agree to amend the Agreement as follows, effective as of the Amendment 3 Effective Date:

1.1 The following Articles are hereby added to Article 1:

> "*1.95 "Amendment 3 Effective Date" shall mean February 24, 2021."*
>
> *"1.96 "Anti-Corruption Laws" shall mean (a) the U.S. Foreign Corrupt Practices Act of 1977 (the "FCPA"), the U.K. Bribery Act 2010, (b) the criminal code of each China Region in the China Territory, (c) the domestic laws of the China Territory and (d) any other similar antibribery or anticorruption Laws in the applicable Licensee Territory*."
>
> *"1.97. "China Regions" shall mean each of mainland China, Hong Kong, Macao and Taiwan. For the purposes of the Agreement, when a reference is made to the term "country" and except as expressly stated otherwise, it shall be construed, with respect to the China Territory, as a China Region*."
>
> "*1.98. "China Territory" shall mean the People's Republic of China, including, for the avoidance of doubt, each of the China Regions*."
>
> *"1.99. "Public Official or Entity" shall mean (a) an individual or entity operating in an official or public capacity on behalf of a Governmental Authority (including physicians, hospital administrators, and other healthcare professionals working for or on behalf of state-controlled healthcare organization), (b) any official or employee of a quasi-public or non-governmental international organization, (c) any employee or other person acting for or on behalf of any entity that is wholly or partially government owned or controlled by a Governmental Authority, (d) any person exercising legislative, administrative, judicial, executive, or regulatory functions for or pertaining to a Governmental Authority (including any independent regulator), (e) any political party official, officer, employee, or other person acting for or on behalf of a political party and (f) any candidate for public office."*

1.2 Article 1.33 is hereby deleted in its entirety and replaced as follows:

> *"Licensee Territory" shall mean Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland,*

Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom, Switzerland, Albania, Bosnia-Herzegovina, Croatia, Kosovo, Republic of Macedonia, Montenegro, Serbia, Tunisia, Algeria, Morocco, Western African Countries, Middle East Countries, South Africa, Sudan, Turkey, the China Territory and any other countries as may be added from time to time pursuant to Article 2.6 or by mutual agreement."

1.3 Article 1.50 is hereby deleted in its entirety and replaced as follows:

"Major Markets" shall mean [***]."

1.4 Article 1.75 is hereby deleted in its entirety and replaced as follows:

"Product Trademarks" shall mean: (a) the product-specific Trademarks owned or Controlled by Licensor and designated by Licensor for use with the Product in the Licensee Territory, as reflected on EXHIBIT 5; and (b) any other product-specific Trademark(s) Controlled by Licensor in connection with the distribution, marketing, promotion and sale of the Product in the Licensee Territory, or accompanying logos, trade dress or indicia of origin."

1.5 The following Licensed Patents are added to the end of Exhibit 1 (Licensed Patents):

1.6 The following Product Trademarks are added to the end of Exhibit 5 (Product Trademarks):

2. FINANCIALS

2.1 The following Articles are hereby added to Article 6:

"6.9. Financial Conditions with Respect to the China Territory.

6.9.1 License Fee. In partial consideration of (i) the extension of the Licensee Territory to include the China Territory (ii) Licensor's causing CANbridge to enter into the TSA, Licensee will pay Licensor the sum of $50,000,000 within [***] ([***]) Business Days of the Amendment 3 Effective Date.

6.9.2 Milestone Payments.

(a) Development Milestone Payments. In further consideration for the exclusive rights and licenses granted by Licensor to Licensee hereunder for the China Territory, Licensee shall pay to Licensor the milestone payment set out below following the first achievement by Licensee, and/or any of its Affiliates or Sublicensees with respect to the China Territory, of the corresponding milestone event set out below with respect to the Product, in accordance with this Article 6.9.2 and the payment provisions in Article 7:

Milestone Event	***Milestone Payment***
[***]	*[***]*

(b) Sales Milestone Payments. In further consideration for the exclusive rights and licenses granted by Licensor to Licensee hereunder with respect to the China

Territory, Licensee shall pay to Licensor the milestone payments set out below following the first time that the Annual Royalty Bearing Net Sales of the Product in the China Territory reach the following thresholds, in accordance with this Article 6.9.2 and the payment provisions in Article 7 ("China Territory Sales Milestones"):

Sales Milestone Events in China Territory	***Milestone Payment***
[***]	*[***]*
[***]	*[***]*
[***]	*[***]*
[***]	*[***]*
[***]	*[***]*

(c) Articles 6.2(d) and 6.3 shall apply mutatis mutandis to this Article 6.9.

(d) With respect to the China Territory Sales Milestones, each such China Territory Sales Milestone payment shall be payable only once, provided that if two (2) or more China Territory Sales Milestones are due and payable during the same Calendar Year, then Licensee may pay only the higher China Territory Sales Milestone payment due and payable during such Calendar Year and the payment of the lower China Territory Sales Milestone(s) would be deferred to the subsequent Calendar Year (any such deferred China Territory Sales Milestone payment amount, collectively, "Deferred China Territory Sales Milestone Amount"). For the avoidance of doubt, if one (1) or more Sales Milestones are due and payable during the same Calendar Year with respect to Annual Royalty Bearing Net Sales in the Licensee Territory excluding the China Territory, and (1) or more China Territory Sales Milestones are due and payable during the same Calendar Year with respect to Annual Royalty Bearing Net Sales in the China Territory, then Licensee must pay the higher Sales Milestone in accordance with Article 6.2(c) for the Annual Royalty Bearing Net Sales in the Licensee Territory excluding the China Territory, on the one hand, and the higher China Territory Sales Milestone in accordance with this Article 6.9.2(d) with respect to Annual Royalty Bearing Net Sales in the China Territory, on the other hand, and may defer the Deferred Sales Milestones in the Licensee Territory excluding the China Territory and the Deferred China Territory Sales Milestones for the China Territory, respectively, to the subsequent Calendar Year in accordance with the terms of this Agreement.

6.9.3 Royalties.

(a) During the Royalty Term, Licensee shall pay to Licensor, on a [***] basis, a royalty on the Annual Royalty Bearing Net Sales of the Product in the China Territory by Licensee, its Affiliates or Sublicensees ("China Territory Royalty Payments"). The amount of China Territory Royalty Payments shall be paid [***], at the applicable rates set forth below, based on the Annual Royalty Bearing Net Sales of the Product in the China Territory. For clarity, and notwithstanding anything to the contrary under Article 6.4(a), the Royalty Payments defined in Article 6.4 shall exclude any and all China Territory Royalty Payments. Furthermore, the royalty rates set forth in Article 6.4(a) shall only apply to those

Annual Royalty Bearing Net Sales of the Product in the Licensee Territory excluding the China Territory by Licensee, its Affiliates or Sublicensees.

Annual Royalty Bearing Net Sales in a Given Calendar Year in the China Territory	***Royalty Rate***
With respect to the portion of Annual Royalty Bearing Net Sales lower than or equal to [***]	*[***]%*
With respect to the portion of Annual Royalty Bearing Net Sales higher than [***] but lower than or equal to [***]	*[***]%*
With respect to the portion of Annual Royalty Bearing Net Sales higher than [***]	*[***]%*

(b) Notwithstanding Article 6.9.3(a), [***].

(c) Articles 6.4(b) and 6.4(c) shall apply mutatis mutandis to this Article 6.9.

(d) The adjustments set forth in Articles 6.5 and 6.6 shall apply mutatis mutandis to this Article 6.9.3.

6.9.4. Clarification. The Parties hereby agree that, for the purposes of calculating the Annual Royalty Bearing Net Sales thresholds in Articles 6.2(b) and 6.4(a), the Licensee Territory shall exclude the China Territory."

2.2 The last sentence of Article 7.4(a) is hereby deleted and replaced by the following sentences:

"Notwithstanding anything to the contrary in this Article 7.4(a), the Parties acknowledge and agree that Licensee will not, absent a change in Law or relevant circumstance between the date of this Agreement and the applicable date of payment, deduct or withhold from the amounts payable pursuant to Articles 6.1, 6.2, 6.4, 6.5 or 6.9 any amount in respect of any taxes provided that Licensor provides Licensee with applicable Tax Documentation establishing an exemption from withholding under Article 12 of the 1994 income tax treaty between the government of the United States and the French Republic (as amended by the 2006 protocol and the 2009 protocol)."

3. REGULATORY

3.1 The following sentence is hereby added at the end of Article 4.3(c):

"Notwithstanding the foregoing, with respect to any Shared Clinical Trial initiated after the Amendment 3 Effective Date by Licensee involving Clinical Study centres or sites located both in the China Territory and the Licensee Territory excluding the China Territory ("Additional Licensee Multi-Territory Clinical Study"), Licensee shall bear [***] percent ([***]%) of the costs of the applicable Shared Development Budget and Licensor shall bear [***] percent ([***]%) of the applicable Shared Development Budget."

3.2 Article 4.3(e) is hereby deleted in its entirety and replaced as follows:

"If upon completion of an Additional Clinical Study by Licensee, Licensor wishes to use any Data arising out of such Additional Clinical Study in a substantive manner by filing the same with a Regulatory Authority (either directly or by reference) in Licensor's respective territory as the basis for obtaining new or expanded Marketing Approval for the Product for the same Indication that was the subject of such Additional Clinical Study, Licensor shall reimburse Licensee as follows:

i. *If such Additional Clinical Study was an Additional Licensee Multi-Territory Clinical Study, then [***] percent ([***]%) of [***] percent ([***]%) of the applicable Shared Development Budget determined pursuant to Article 4.3(c) (i.e., [***]% of the Shared Development Budget); and*

ii. *If such Additional Clinical Study was conducted only in the China Territory or only in the Licensee Territory excluding the China Territory, then [***] percent ([***]%) of [***] percent ([***]%) of the applicable Shared Development Budget determined pursuant to Article 4.3(c) (i.e., [***]% of the Shared Development Budget).*

If upon completion of an Additional Clinical Study by Licensor, Licensee wishes to use any Data arising out of such Additional Clinical Study in a substantive manner by filing the same with a Regulatory Authority (either directly or by reference) either in the China Territory or the Licensee Territory excluding the China Territory, in each case, as the basis for obtaining new or expanded Marketing Approval for the Product for the same Indication that was the subject of such Additional Clinical Study, Licensee shall reimburse Licensor [***] percent ([***]%) of [***] percent ([***]%) of the applicable Shared Development Budget determined pursuant to Article 4.3(c) (i.e., [***]% of the Shared Development Budget). Notwithstanding the foregoing, if Licensee wishes to use such Data for both the China Territory and the Licensee Territory excluding the China Territory, then Licensee shall reimburse Licensor [***] percent ([***]%) of [***] percent ([***]%) of the applicable Shared Development Budget determined pursuant to Article 4.3(c) (i.e., [***]% of the Shared Development Budget)."

3.3 The following Article 4.10 is hereby added to Article 4:

"4.10. <u>Regulatory Filings and Marketing Approvals in the China Territory</u>.

(a) *Licensor shall transfer or cause CANbridge or its affiliates to transfer to Licensee or its Affiliates or their designees all Regulatory Filings, Marketing Approvals and Pricing and Reimbursement Approvals, if any, for the Product in the Field in the China Territory in accordance with the timeline specified in the TSA.*

(b) ***Mainland China**. Licensor shall use Commercially Reasonable Efforts to (i) take all reasonably necessary actions to remove CANbridge or its affiliates as the "local agent" in connection with any Marketing Approval and Pricing and Reimbursement Approval (if applicable) issued by the National Medical Products Administration ("**NMPA**") of the mainland China for the Product, and cause CANbridge or its affiliates to comply with the foregoing, and appoint Licensee or its Affiliate as the "local agent" in connection with such Marketing Approval and Pricing and Reimbursement Approval (if applicable), and (ii) transfer such Marketing Approval and Pricing and Reimbursement Approval (if applicable) to*

Licensee or its designee. Licensee shall use Commercially Reasonable Efforts to take all reasonably necessary actions to (x) appoint itself or its Affiliate as the "local agent" of Licensor in connection with such Marketing Approval and Pricing and Reimbursement Approval (if applicable) and (y) transfer such Marketing Approval and Pricing and Reimbursement Approval (if applicable) to itself, its Affiliates or a designee.

(c) ***Taiwan.*** *Licensee shall assess and discuss in good faith with Licensor as to whether it is commercially reasonable to (i) terminate, cancel or otherwise deregister the Marketing Authorization granted to CANbridge or its Affiliate by the Taiwan Food and Drug Administration that references PUMA's Marketing Authorization approved by the FDA for the Product and (ii) register a new Marketing Authorization in Taiwan that references Licensee's Marketing Approval as approved by the EMA for the Product. If Licensee, in its reasonable discretion, determines that the above (i) and (ii) are not commercially reasonable, then Licensee may maintain the Marketing Authorization granted by the Taiwan Food and Drug Administration that references PUMA's Marketing Authorization approved by the FDA for the Product.*

(d) ***Hong Kong****. Licensee shall assess and discuss in good faith with Licensor as to whether it is commercially reasonable to (i) terminate, cancel or otherwise deregister the Marketing Authorization granted to CANbridge or its Affiliate by the Pharmacy and Poisons Board of Hong Kong that references PUMA's Marketing Authorization approved by the FDA for the Product and (ii) register a new Marketing Authorization in Hong Kong that references Licensee's Marketing Approval as approved by the EMA for the Product. If Licensee, in its reasonable discretion, determines that the above (i) and (ii) are not commercially reasonable, then Licensee may maintain the Marketing Authorization granted by the Pharmacy and Poisons Board of Hong Kong that references PUMA's Marketing Authorization approved by the FDA for the Product.*

(e) *Before the applicable transfer, termination, cancelation, deregistration or registration of the applicable Marketing Approval and Pricing and Reimbursement Approvals, if any, in the applicable China Region of the China Territory, Licensor shall (i) not take or omit to take any material action or make any material communication with respect to any Regulatory Filings or such Marketing Approval and/or Pricing and Reimbursement Approvals, if any, for the Product in the relevant China Region of the China Territory without Licensee's prior written consent unless it is required to do so under Law (in which case it shall use good faith efforts to consult with Licensee in advance of such action) and (ii) promptly transmit to Licensee any communication received from or draft of any planned communication or submission to the relevant Regulatory Authorities with respect to any such Marketing Approval and Pricing and Reimbursement Approvals, if any, and shall use good faith efforts to cause CANbridge or its affiliates to comply with the foregoing (i) and (ii)."*

3.4 The Parties shall use good faith efforts to amend the Safety Data Exchange Agreement to include the China Territory no later than [***] ([***]) Business Days after the Amendment 3 Effective Date, unless otherwise agreed by the Parties.

3.5 ***Governance***. The Parties will form a specific working group dedicated to the China Territory, which will coordinate transition activities with respect to the China Territory.

(a) Accordingly, the following paragraph (vi) is hereby added to Article 3.2(b):

"(*vi) a Working Group dedicated to the China Territory to coordinate a smooth and efficient transition of the ongoing activities with respect to the Product in the China Territory pursuant to the TSA, and to coordinate and share information with respect to the Development and Commercialization of the Product in the China Territory, including communications with the Regulatory Authorities in the China Territory."*

(b) The following Article 3.6 is hereby added to Article 3:

"*In accordance with Section 3.2 of the TSA, Licensee shall provide Licensor with a meeting summary for each meeting held between Licensee and/or its Affiliates and CANbridge and/or its affiliates to discuss the status of the transition of the Product and related issues thereto, in accordance with the terms of the TSA, in the English language and in reasonable detail, at least [***]*."

3.6 ***Commercialization***. The following Article 5.2 is hereby added to Article 5:

"(a) Licensee may appoint CANbridge or one of its affiliates as its distributor in Hong Kong, Taiwan and Macao, for the purposes of (i) importing, distributing and promoting the Product and (ii) seeking and maintaining the relevant Regulatory Filings necessary for the performance of its obligation pursuant to the Ancillary Agreements, in such China Regions, and for no other purpose, and in accordance with the terms of the Ancillary Agreements, it being specified that in such event, as between Licensor and Licensee (x) CANbridge and its affiliates shall not be deemed Sublicensees but distributors for the purposes of the Agreement, including for the computation of Net Sales, notwithstanding Section 1.85, and (y) Puma consents to CANbridge or its affiliates acting as Licensee's distributor in Hong Kong, Taiwan and Macao pursuant to this Article 5.2(a) until [***], which term may be renewed for up to [***] with Licensor's prior written consent, which consent shall not be unreasonably withheld or delayed as long as CANbridge complies with its obligations pursuant to the CANbridge Agreement. In no event shall CANbridge or its affiliates perform any Development activities without the prior written consent of Licensor.

(b) Notwithstanding the foregoing, [***].

(c) The foregoing Article 3.6(b) shall apply to any other Third Party in the event an agreement between Licensee and such Third Party contemplates similar rights and/or payment structure in Hong Kong, Taiwan and/or Macao as in the CANbridge Agreement. In such event, Article 3.6(b) shall apply mutatis mutandis to such agreement with such Third Party.

*(d) Licensee may appoint SPH KDL HEALTH (SHANGAI) PHARMACEUTICAL Co, LTD ("**SPH**") or one of its affiliates as its distributor in mainland China for the purposes of importing and distributing the Product in such China Region, and for no other purpose, it being specified that in such event, SPH and its affiliates shall not be deemed Sublicensees but distributors for the purposes of this Agreement, including for the computation of Net Sales.*

(e) As of Amendment 3 Effective Date, other than the Ancillary Agreements, there are no other agreements, contracts, letters or understandings, whether written or oral, between CANbridge or its Affiliates and Licensee or its Affiliates. Notwithstanding anything to the contrary under this Article 5.2, Licensee shall provide Licensor any material amendments to an Ancillary Agreements or any new material agreements between Licensee and CANbridge, or any of their Affiliates, that relate to the importing, distributing and promoting of the Product in Hong Kong, Taiwan and Macao, to the extent such agreement may materially affect CANbridge's rights and obligations and/or the financial structure of the Ancillary Agreements."

4. SUPPLY AND MANUFACTURING

4.1 The following Article 8.5 is hereby added to Article 8:

"8.5 The Supply Agreement (and the related quality agreement) shall be amended to include the China Territory, provided that until the amendments to the applicable Regulatory Filings and/or Marketing Authorizations for the Product are approved by the applicable Governmental Authorities for a given China Region, Licensor shall supply the Finished Product to Licensee for such China Region at [***]. Licensee and Licensor shall use good faith efforts to promptly, and no later than [***] ([***]) Business Days after the Amendment 3 Effective Date, to formalize the amendment of the Supply Agreement, unless otherwise agreed by the Parties.

5. TERMINATION AND EFFECT OF TERMINATION

5.1 The following is added to the end of Article 12.2:

"Notwithstanding anything to the contrary herein, including this Article 12.2, Licensor will have the right, but not the obligation, to terminate this Agreement solely with respect to any China Region in accordance with Section 12.7 immediately upon written notice to Licensee for any material breach of Articles 14.3(f), 14.6 and 14.7 of this Agreement that results in a material violation of the Anti-Corruption Laws by Licensee, its Affiliates, Sublicensees or contractors in such China Region, provided that if the China Region is mainland China, Licensor shall be entitled to terminate the Agreement with respect to the entire China Territory, and provided further that if the material breach is due to a Sublicensee or distributor of Licensee, Licensor shall not be entitled to terminate this Agreement with respect to the relevant China Region if Licensee immediately terminates in whole the relevant Sublicense or distribution agreement."

5.2 Article 12.7 is hereby deleted in its entirety and replaced as follows:

"*Termination; Partial Termination. This Agreement may not be terminated by Licensee under Article 12.4 (Termination for Convenience), 12.5 (Termination for Safety Reasons) or by either Party for cause under Article 12.2 (Termination for Material Breach) or for bankruptcy under Article 12.3 (Termination for Bankruptcy) on a country-by-country or other partial basis. Notwithstanding the foregoing, this Agreement may be terminated by Licensee under Article 12.4 (Termination for Convenience), 12.5 (Termination for Safety Reasons) or by either Party for cause under Article 12.2 (Termination for Material Breach) or for bankruptcy under Article 12.3 (Termination for Bankruptcy) for (i) the Licensee Territory excluding the China Territory or (ii) the China Territory (either (i) or (ii), a "Partial Termination"). Upon the effective date of any Partial Termination, the Licensee Territory shall no longer include the portion(s) of the Licensee Territory set forth in the relevant termination notice.*"

5.3 The last sentence of Article 13.1 is deleted in its entirety and replaced with the following:

> "*Any Partial Termination of this Agreement in accordance with Article 12.7 for any reason shall not release either Party from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination, nor will any such termination preclude either Party from pursuing all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement, provided that any milestone payment that is achieved under Article 6.2 or Article 6.9, as applicable, during the termination notice period shall be reduced by [***] ([***]%). For clarity, any Deferred Sales Milestone Amount and China Territory Deferred Sales Milestone Amount shall not be subject to the foregoing reduction."*

5.4 The last paragraph of Article 13.2(a) is deleted in its entirety and replaced with the following:

> *"[***]."*

5.5 Article 13.2(b) is deleted in its entirety and replaced with the following:

> *"Each Party shall pay to the other Party all amounts due to the other Party with respect to the Shared Development Budget, Post-Approval Marketing Study Costs and any Deferred Sales Milestone Amount or Deferred China Territory Sales Milestone Amount, as applicable, accrued and unpaid as of the effective date of termination or expiration, within [***] ([***]) days following the effective date of termination or expiration. For clarity, in case of a Partial Termination of this Agreement in accordance with Article 12.7, then this Article 13.2(b) shall apply solely to costs incurred with respect to the terminated portion of the Licensee Territory."*

5.6 The following paragraphs are added to the end of Articles 13.2(c), (d), (e), (g) and (h), respectively:

> *"For clarity, notwithstanding anything to the contrary in this Article 13.2, in case of a Partial Termination of this Agreement in accordance with Article 12.7, then this Article 13.2(c) shall apply solely to the terminated portion of the Licensee Territory."*
>
> *"For clarity, notwithstanding anything to the contrary in this Article 13.2, in case of a Partial Termination of this Agreement in accordance with Article 12.7, then this Article 13.2(d) shall apply solely to the terminated portion of the Licensee Territory."*
>
> *"For clarity, notwithstanding anything to the contrary in this Article 13.2, in case of a Partial Termination of this Agreement in accordance with Article 12.7, then this Article 13.2(e) shall apply solely to the terminated portion of the Licensee Territory."*
>
> *"For clarity, notwithstanding anything to the contrary in this Article 13.2, in case of a Partial Termination of this Agreement in accordance with Article 12.7, then this Article 13.2(g) shall apply solely to the terminated portion of the Licensee Territory."*
>
> *"For clarity, notwithstanding anything to the contrary in this Article 13.2, in case of a Partial Termination of this Agreement in accordance with Article 12.7, then this Article 13.2(h) shall apply solely to the terminated portion of the Licensee Territory."*

5.7 Article 13.2(f) is deleted in its entirety and replaced with the following:

> *"Return of Confidential Information. Within thirty (30) days after the end of the Wind-down Period upon request by Licensor, Licensee shall either return to Licensor or destroy all tangible items comprising, bearing or containing Confidential Information of Licensor, that is in Licensee's possession, subject to Licensee's right to keep one copy for archiving purposes, provided, that, in case of a Partial Termination of this Agreement in accordance with Article 12.7, Licensee shall either return to Licensor or destroy any Confidential Information that solely relates to the terminated portion of the Licensee Territory at Licensor's sole option."*

5.8 Article 13.3 is deleted in its entirety and replaced with the following:

> *"Upon the expiration or termination of this Agreement in its entirety, all rights and obligations of the Parties under this Agreement shall terminate, or upon Partial Termination of this Agreement, all rights and obligations of the Parties solely with respect to the terminated portion of the Licensee Territory shall terminate, and in each case, except those which are expressly or by their nature set to survive such expiration or termination as well as those described in the following: Articles: 1, 2.2, 2.3(a), 2.4, 2.8, 7, 9, 10.1, 12.7, 13, 15 (solely to the extent Third Party Claims were incurred during the term of this Agreement), 17.2 through 17.8 (inclusive), 17.10 through 17.13 (inclusive)."*

6. REPRESENTATIONS, WARRANTIES AND COVENANTS OF LICENSEE

6.1 Article 14.1(c) shall not apply to the China Territory, for which the provisions below that are more specific shall apply

6.2 The following is added as Article 14.3(f):

> *"To each Party's knowledge, no officer, director, or employee of such Party or its Affiliates (an "Interested Person"), is a Public Official or Entity or Governmental Authority in the China Territory."*

6.3 The following is added as a new Article 14.6:

> *"14.6. Licensee with respect to itself and its Affiliates that have been or will be involved in the Development, Regulatory Filing activities and/or Commercialization of the Product in the China Territory represents, warrants to Licensor that, as of the Amendment 3 Effective Date, and Licensor represents, warrants to Licensee that, as of the Amendment 3 Effective Date, to the knowledge of such Party's compliance department:*
>
> *(a) neither they or their directors, officers, employees, or any Person authorized to act on its behalf have violated any Anti-Corruption Law in the China Territory;*

(b) *neither they nor any Person acting on its behalf, has offered, given, authorized, or promised anything of value (as defined by applicable Anti-Corruption Laws), either directly or indirectly, to any Person, including to any Public Official or Entity, for the purpose of (i) improperly influencing any official act or decision; (ii) inducing performance or non-performance of any act in violation of a lawful duty; or (iii) securing an improper benefit or business advantage, in each case ((i) – (iii)) in any manner that violates the applicable Anti-Corruption Laws in the China Territory;*

(c) *they have not received any written notice, request, or citation from any Governmental Authority with respect to any alleged or suspected violation of Anti-Corruption Laws in the China Territory;*

(d) *they are not under investigation or being prosecuted by a Governmental Authority with respect to any alleged or suspected violation of Anti-Corruption Laws in the China Territory;*

6.4 The following is added as a new Article 14.7:

"*14.7 Covenants of Licensee. Licensee hereby covenants to Licensor that it shall, and shall cause its Affiliates, Sublicensee and contractors involved in the Development, Regulatory Filing activities and/or Commercialization of the Product in the China Territory to*

(a) *comply in all material respects with all applicable Laws with respect to the performance of its and their activities pursuant to this Agreement in the China Territory;*

(b) *comply with the Anti-Corruption Laws (as modified or amended) in the China Territory;*

(c) *not, directly or indirectly, offer or pay, or authorize such offer or payment of, any money, or transfer anything of value (as defined by applicable Anti-Corruption Laws), for purposes of improperly seeking to influence any Public Official or Entity or Governmental Authority in any manner that violates applicable Anti-Corruption Laws in connection with this Agreement in the China Territory;*

(d) *reasonably cooperate with Licensor and its Affiliates in ensuring compliance with (i) the Anti-Corruption Laws, (ii) any restrictions concerning the export of products or technical information which may be imposed upon or related to the Parties from time to time ("Export Control Laws") and (iii) all other applicable Laws, in each case, in the China Territory;*

(e) *provide Licensor with any information reasonably requested by Licensor in connection with its efforts to ensure compliance with applicable Laws in connection with the performance of this Agreement with respect to the China Territory;*

(f) *promptly notify Licensor if Licensee becomes aware of any material information that would reasonably suggest that there may be a violation of the Anti- Corruption Laws, Export Control Laws or any other applicable Law in connection with the performance of this Agreement or the sale of the Product in the China Territory; and*

(g) *promptly following discovery, notify Licensor if (i) any Interested Person becomes a Public Official or Entity or Governmental Authority or (ii) any Public Official or Entity or Governmental Authority acquires a legal or beneficial interest in Licensee or any of its Affiliates or Sublicensees or contractors in the China Territory."*

6.5 The following is hereby added as a new Article 14.8:

"14.8 No Diversion. Each Party hereby covenants and agrees that it and its Affiliates shall not, and it shall contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its licensees, sublicensees and contractors not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like (a) in the case of Licensee, from the China Territory to Licensor's territory (worldwide excluding the Licensee Territory) and (b) in the case of Licensor, from Licensor's territory to the China Territory. Neither Party shall engage, nor permit its Affiliates, sublicensees or contractors to engage, in any advertising or promotional activities relating to any Product for use directed primarily to customers or other buyers or users of such product located in any country, region or jurisdiction in the such other Party's territory as stated in clause (a) and (b), respectively, or solicit orders from any prospective purchaser located in any country, region or jurisdiction in the other Party's territory, as stated in clause (a) and (b)."

7. MISCELLANEOUS.

7.1 Choice of Law; Dispute Resolution. All disputes between Licensor and Licensee arising from the rights and obligations of the Parties under this Amendment or the Agreement (whether based on contract, tort, or any other theory) shall be resolved pursuant to Article 16 and Article 17.2 of the Agreement.

7.2 Third Party Beneficiary Rights under the Termination Agreement. As between Licensor and Licensee, Licensor waives the right to make any claims against CANbridge in accordance with Article 5 of the Termination Agreement and Licensee shall have the sole right and benefit to make any claims against CANbridge under Article 5 of the Termination Agreement. Licensee shall not recover more than once for the same damages, losses and/or liabilities, including any Losses, as defined under the CANbridge License Agreement as a third party beneficiary of the Termination Agreement in accordance with Section 10.10 therein, but shall be entitled to recover the full amount of such damages, losses and/or liabilities, including any Losses, to the extent permitted by the Termination Agreement.

7.3 Entire Agreement. This Amendment, together with the Agreement, constitutes the sole and entire agreement of the Parties with respect to the subject matter hereof, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter.

7.4 Representations and Warranties. With the exception of those set forth in Schedule 7.4 herein, each Party hereby represents and warrants to the other Party that: (a) it has the full right, power and authority to enter into this Amendment and to perform its obligations hereunder and under the Agreement as amended by this Amendment; (b) the execution of this Amendment by the individual whose signature is set forth at the end of this Amendment on behalf of such Party, and the delivery of this Amendment by such Party, have been duly authorized by all necessary action on the part of such Party; and (c) this Amendment has been executed and delivered by such Party and (assuming due authorization, execution and delivery by the other Party hereto) constitutes the legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms. Licensor further represents and warrants to Licensee that (i) the CANbridge Agreements have been terminated as of the Amendment 3 Effective Date, (ii) neither CANbridge nor any of its affiliates and their respective, officers, directors, successors, assigns, employees, attorneys, advisors and agents have any claims against the Licensor based upon, arising out of, related to, or in connection with any act or omission of a Party under the CANbridge Agreements prior to the Amendment 3 Effective Date. The Licensor hereby irrevocably undertakes to indemnify and hold harmless the Licensee, its affiliates and their respective, officers, directors, successors, assigns, employees, attorneys, advisors and agents from and against any and all claims, liabilities, obligations, damages, penalties, fines, judgments, proceedings, costs, expenses and losses (including amounts paid in settlement, costs of investigation and reasonable attorney's fees and expenses) resulting from or relating to any claim, known or unknown, asserted or unasserted having its source or origin in the CANbridge Agreements prior to the Amendment 3 Effective Date.

7.5 Limited Effect. Except as modified by this Amendment, all other terms and conditions of the Agreement remain in full force and effect.

7.6 Counterparts. This Amendment may be executed in counterparts via the exchange of documents and signatures between Latham & Watkins LLP, 140 Scott Drive, Menlo Park, CA 94025, and McDermott Will & Emery LLP, 200 Clarendon Street, Floor 58, Boston, MA 02116-5021, each of which shall be deemed an original, but all of which shall constitute one and the same agreement. Delivery of an executed counterpart of this Amendment electronically shall be as effective as delivery of an original signed counterpart of this Amendment.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have duly executed and delivered this Amendment as of the Amendment 3 Effective Date.

PUMA BIOTECHNOLOGY, INC.

By: /s/ Alan H. Auerbach

Name: Alan H. Auerbach
Title: Chief Executive Officer

PIERRE FABRE MEDICAMENT SAS

By: /s/ Jean-Luc Lowinski

Name: Jean-Luc Lowinski
Title: President

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Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alan H. Auerbach, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2021;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Maximo F. Nougues, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2021;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

/s/ Maximo F. Nougues
Maximo F. Nougues
Chief Financial Officer

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2021, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Executive Officer

I, Alan H. Auerbach, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2021, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: May 6, 2021

/s/ Alan H. Auerbach
Alan H. Auerbach
Principal Executive Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The following certification is being furnished solely to accompany the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2021, pursuant to 18 U.S.C. § 1350 and in accordance with SEC Release No. 33-8238. This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any filing of Puma Biotechnology, Inc. under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Certification of Principal Financial Officer

I, Maximo F. Nougues, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Puma Biotechnology, Inc. for the quarter ended March 31, 2021, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of Puma Biotechnology, Inc.

Date: May 6, 2021

/s/ Maximo F. Nougues
Maximo F. Nougues
Principal Financial and Accounting Officer

A signed original of this written statement required by Section 906 has been provided to Puma Biotechnology, Inc. and will be retained by Puma Biotechnology, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.